**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

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| DALE TRSAR, TRUSTEE OF THE DALE A. TRSAR TRUST, on behalf of himself and all others similarly situated and derivatively on behalf of AKORN, INC., | |
| Plaintiff, | Case No. 1:18-cv-07374 |
| vs. | |
| JOHN N. KAPOOR, RAJAT RAI, MARK M. SILVERBERG, DUANE A. PORTWOOD, ALAN WEINSTEIN, KENNETH S. ABRAMOWITZ, STEPHEN J. MEYER, TERRY ALLISON RAPPUHN, ADRIENNE L. GRAVES, RONALD M. JOHNSON, and BRIAN TAMBI, | |
| Defendants, | JURY TRIAL DEMANDED |
| – and – | |
| AKORN, INC., | |
| Defendant and Nominal Defendant. | |

**VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT**

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Plaintiff Dale Trsar, Trustee of the Dale A. Trsar Trust ("Plaintiff"), by and through the undersigned attorneys, brings this action derivatively on behalf of nominal defendant Akorn, Inc. ("Akorn" or the "Company") and alleges the following based upon personal knowledge as to himself and his own acts, and upon information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys. This investigation included, among other things, a review of the defendants' public documents and announcements; the Company's conference calls and press releases; United States Securities and Exchange Commission ("SEC") filings; press releases and news reports published regarding Akorn; corporate governance and other documents available on the Company's website; court filings in lawsuits involving Akorn, including *Akorn, Inc. v. Fresenius Kabi AG*, C.A. No. 2018-0300-JTL (Del. Ch.); and other publicly-available information about the Company. Counsel's investigation into the factual allegations continues, and many of the relevant facts are exclusively within Defendants' custody or control. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth below after a reasonable opportunity for discovery.

## NATURE OF THE ACTION

1. This is an action seeking to hold Akorn's board of directors ("Board") and senior management accountable for their breaches of fiduciary duty, unjust enrichment, and violations of Section 14A of the Securities Exchange Act ("Exchange Act").

2. Between 2014 and the present (the "Relevant Period"), the Defendants knowingly failed to address Akorn's non-compliance with Food and Drug Administration ("FDA") rules designed to ensure the safety and efficacy of pharmaceutical products. The Individual Defendants' failure to ensure these serious issues were addressed breached their fiduciary duties and caused massive harm to Akorn.

3. Moreover, during the Relevant Period, despite being repeatedly advised of Akorn's pervasive non-compliance with FDA rules designed to ensure the safety and efficacy of pharmaceutical products, the Individual Defendants caused Akorn to make knowingly false statements to the contrary in Akorn's Proxy Statements filed with the SEC.

4. The Board's misconduct came to light after Akorn entered into a merger agreement ("Merger Agreement") with Fresenius SE & Co. KGaA ("Fresenius SE" and, together with Fresenius Kabi AG, "Fresenius"), a German healthcare provider.

5. Under the terms of the Merger Agreement, Fresenius would acquire all the stock of Akorn in an all-cash deal valued at $4.3 billion.

6. While doing due diligence in advance of the merger, Fresenius received three letters from purported whistleblowers. These letters alleged that (among other things) Akorn's research and development activities were significantly "flawed and … mostly corrupted or incomplete."

7. Prompted by the whistleblowers' allegations, Fresenius opened an investigation into their claims. The results were astounding — showing a pattern and practice of knowing violations of FDA regulations and provision of falsified clinical test results to the FDA. Among other things, the investigation revealed that: (a) Akorn's senior management and Board were aware of the serious violations long before entering into the Merger Agreement and had failed to remediate them; (b) Akorn's Board executed the Merger Agreement even though it included false representations concerning Akorn's compliance with FDA rules; and (c) even following the execution of the Merger Agreement, Akorn's Board and senior management continued to be informed of serious regulatory violations — including a risk of potential criminal liability — but hid those violations rather than fixing them.

8. As a result of these findings, Fresenius concluded that Akorn was in material breach of the Merger Agreement and cancelled the transaction in April 2018. Akorn sued Fresenius in the Delaware Chancery Court to force Fresenius to close the deal. The companies went to trial over the merger in July 2018.

9. On October 1, 2018, Vice Chancellor Laster found in favor of Fresenius and canceled the Merger Agreement once and for all. In his Memorandum Opinion, the Vice Chancellor stated that he ruled in favor of Fresenius "because Akorn's representations regarding its compliance with regulatory requirements were not true and correct, and the magnitude of the inaccuracies would reasonably be expected to result in a Material Adverse Effect." He explained that "the extensive and recurring quality and data integrity problems at Akorn convinced [him] that Akorn did not have a well-functioning quality system and lacked a meaningful culture of compliance."

10. The facts revealed during trial show that when Akorn's Board learned about the serious data integrity and regulatory violations at Akorn, rather than remediating them, they instead hid them while trying to find a merger partner so that they could foist the Company's problems on the acquirer. This strategy would have provided a windfall for the Director Defendants but instead has left Akorn in shambles and damaged it by millions of dollars in legal fees, costs, and expenses.

11. The fallout from this debacle has devastated Akorn. Akorn's market capitalization as of October 3, 2018 was ***$720 million***, a mere fraction of its $34 dollar per share or ***$4.3 billion value*** when the Merger Agreement was executed. It will cost Akorn an estimated $900 million to remediate its serious regulatory issues, and it is still unknown what regulatory steps the FDA will take, but it could impose huge fines on the Company and place severe limitations on the Company's approved products and pipeline of new products.

12. Plaintiff brings this action to hold Akorn's directors and officers accountable for the damage they have caused to the Company through their wrongdoing.

## PARTIES

### I. Plaintiff

13. Plaintiff Dale Trsar, Trustee of the Dale A. Trsar Trust is an owner of Akorn common stock, and has held this stock continuously since at least June 2015. On June 29, 2018, Mr. Trsar sent a demand pursuant to LA Rev. Stat. § 12:1-742 to the Akorn Board of Directors (the "Demand"). The demand is attached hereto as Exhibit A.

### II. Director Defendants

14. John N. Kapoor, Akorn's founder, served as Chairman of the Board from October 1990 until he resigned on October 30, 2017. He also served as Akorn's CEO from March 2001 until December 2002. Kapoor also founded and controls the pharmaceutical company Insys Therapeutics ("Insys").

15. Alan Weinstein became a director of the Company in July 2009 and was appointed as Chairman of the Board in 2017. Weinstein also serves as a director on the board of OpenMarkets, which provides a services and technology platform for efficiently purchasing healthcare equipment, and on the board of trustees of the Rosalind Franklin University of Medicine and Science.

16. Kenneth S. Abramowitz became a director of the Company in May 2010. Abramowitz is Managing General Partner of NGN Capital, a venture capital firm that he co-founded in 2003, which focuses on investments in the healthcare and biotechnology sectors.

17. Stephen J. Meyer became a director of the Company in June 2009. Meyer also serves as the chairman of the board of directors and as chair of the audit committee of Insys, a

pharmaceutical company founded and controlled by Defendant Kapoor. Insys's flagship product is the opioid Subsys, a fentanyl spray for pain relief.

18. Terry Allison Rappuhn became a director of the Company in April 2015. In February 2016, Rappuhn was elected to the board of directors of Span-America Medical Systems, Inc., a manufacturer of beds and pressure management products for the medical market.

19. Adrienne L. Graves, PhD became a director of the Company in March 2012. Graves is a visual scientist by training. In its February 28, 2018 Form 10-K, Akorn represents that Graves has "a deep knowledge of pre-clinical and clinical development in this sector, regulatory affairs and pharmaceutical sales and marketing."

20. Ronald M. Johnson became a director of the Company in May 2003. In its February 28, 2018 Form 10-K, Akorn represents that Mr. Johnson has "extensive experience in managing regulatory and compliance requirements of the FDA, particularly in pharmaceutical, medical device, biologic and biotechnology industries, as well as a deep knowledge and understanding of FDA policies and procedures regarding cGMP compliance, quality control processes and outcomes reporting."

21. Brian Tambi became a director of the Company in June 2009. Tambi also serves as a director of Insys, a pharmaceutical company founded and controlled by Defendant Kapoor.

22. Defendants Kapoor, Weinstein, Abramowitz, Meyer, Rappuhn, Graves, Johnson, and Tambi are collectively referred to as the "Director Defendants."

**III. Officer Defendants**

23. Defendant Rajat Rai was appointed Interim CEO of the Company in June 2009 and was appointed CEO in May 2010. Prior to joining Akorn, Rai was the President and CEO of Option Care, Inc., a leading provider of home infusion pharmacy and specialty pharmacy services.

24. Defendant Mark M. Silverberg is Executive Vice President of Operations & Technical Services at the Company. Silverberg was previously employed as a Director of Quality Division by Abbott Laboratories.

25. Defendant Duane A. Portwood is Akorn's Chief Financial Officer ("CFO"), a position he has held since October 2015.

## IV. The Company

26. Defendant and Nominal Defendant Akorn is a specialty generic pharmaceutical company organized under the laws of Louisiana and with the principal place of business in Lake Forest, Illinois. Akorn is engaged in the development, manufacture, and marketing of multisource and branded pharmaceuticals. Akorn has manufacturing facilities located in Decatur, Illinois; Somerset, New Jersey; Amityville, New York; Hettlingen, Switzerland; and Paonta Sahib, India. These facilities manufacture ophthalmic, injectable, and specialty sterile and non-sterile pharmaceuticals. Akorn's common stock is publicly traded on the NASDAQ under the trading symbol "AKRX." Akorn is a citizen of Illinois and Louisiana.

## V. Relevant Non-Parties

27. Non-party Fresenius SE is a German partnership limited by shares with its principal place of business in Homburg, Germany. Fresenius has 4 operating divisions: (a) Fresenius Medical Care, a publicly-traded company partly owned by Fresenius that focuses on patients with chronic kidney failure; (b) Fresenius Helios, Germany's largest hospital operator; (c) Fresenius Kabi AG; and (d) Fresenius Vamed, which plans, develops, and manages healthcare facilities.

28. Non-party Fresenius Kabi AG ("Fresenius Kabi") is a German pharmaceutical company with its principal place of business in Homburg, Germany. It is a wholly-owned subsidiary of Fresenius SE. Fresenius Kabi is a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion, and clinical nutrition.

## JURISDICTION AND VENUE

29. This Court has jurisdiction over the claims asserted herein pursuant to Section 27 of the 1934 Act because the claims asserted herein arise under Sections 14(a) and 20(a) of the 1934 Act and Rule 14a-9.

30. This Court has jurisdiction over defendants because each defendant is either a corporation that conducts business in and maintains operations within this District or is an individual with sufficient minimum contacts with this District so as to make the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice.

31. Venue is proper under 28 U.S.C. § 1391(b) because a substantial portion of the transactions and wrongs complained of herein occurred in this District.

32. Finally, Akorn has consented to jurisdiction and venue in the Northern District of Illinois for "any action or proceeding asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the corporation to the corporation or the corporation's shareholders."

## SUBSTANTIVE ALLEGATIONS

### I. Akorn and Its Quality Control Systems

#### A. Akorn Business Model Is Dependent on FDA's Regulatory Approvals

##### 1. Abbreviated New Drug Applications

33. Akorn is a specialty generic pharmaceutical company that develops, manufactures, and markets generic and branded prescription pharmaceuticals as well as private-label over-the-counter consumer healthcare products and animal healthcare products. Akorn purports to specialize in difficult-to-manufacture and higher margin sterile and non-sterile dosage forms, including, but not limited to, ophthalmics, injectables, oral liquids, otics, topicals, inhalants, and nasal sprays. As a pharmaceutical company, Akorn is regulated by the FDA.

34. In order for Akorn to market and sell its products, it must obtain manufacturing and marketing approval from the FDA. This is accomplished through applications known as Abbreviated New Drug Applications ("ANDAs") that demonstrate that the generic drug is bio-equivalent to the original "branded" drug. As part of the ANDA process, Akorn must also submit the results of drug testing to the FDA that demonstrate that it can manufacture a safe and effective product. The data submitted to the FDA must be supported by laboratory notebooks and electronic records. As part of the ANDA submission, Akorn is required to include a certification stating that the "data and information in the submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate."[1]

35. In its presentation to investors at the JPMorgan Healthcare Conference in January 2017, Akorn touted its "large pipeline of pending ANDAs and planned launches," with "92 filings pending with the FDA" with "a total addressable IMS market value of approximately $9.5 billion" and "[o]ver 75 additional ANDAs in various stages of development."

36. As a generic drug manufacturer and marketer, Akorn must not only receive FDA approvals, but also receive them without delay. The first generic drug manufacturer to market a new drug typically ends up with a larger enduring market share than later manufacturers. In addition, "first filers" are awarded 180 days of statutory marketing exclusivity for a product before other competitors can begin distributing their version of it.

**2. Current Good Manufacturing Practices**

37. In addition to submitting ANDAs for its products, Akorn is also required to adhere to current Good Manufacturing Practices ("cGMP"). The cGMP regulations set forth "the minimum current good manufacturing practice for methods to be used in ... the manufacture,

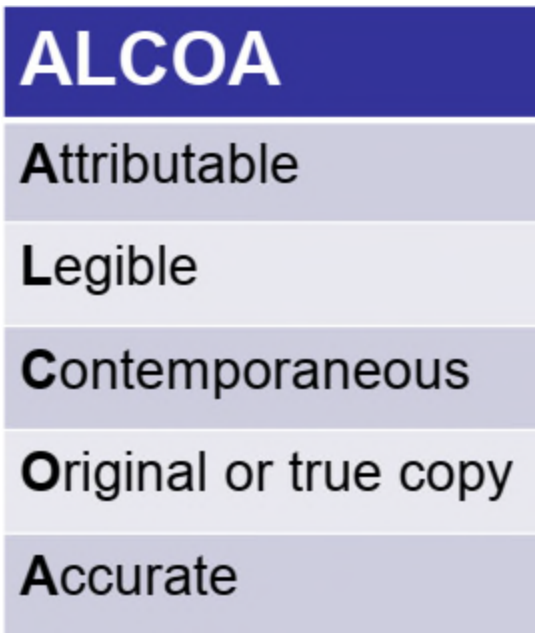
[1] Form FDA 356h – Application to Market a New or Abbreviated New Drug for Human Use, *available at* https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/ucm082348.pdf.

processing, packing, or holding of a drug." 21 C.F.R. § 210.1(a). These requirements are codified, in part, at 21 C.F.R. Pt. 210 and 21 C.F.R. Pt. 211, as well as in FDA guidance, including its April 2016 "*Data Integrity and Compliance with cGMP Guidance for Industry*" draft guidance ("cGMP Guidance"). The cGMP regulations consist of very specific quality-control requirements, which include data integrity requirements, routine testing, and quality monitoring. These are required even after an ANDA has been approved.

38. With regard to "data integrity," the FDA's requirements are designed to ensure that the testing data are complete, consistent, accurate, and free from fraudulent or improper manipulation. Among other things, the FDA's requirements necessitate the implementation of procedures for keeping testing data in a systematic and retrievable manner, protecting it from modification, deletion, or loss, as well as recording and reviewing logs of individual users' actions on computer systems ("audit trails").

39. In its guidance documents, the FDA makes clear that "the requirements for record retention and review do not differ depending on the data format" and, as a result, paper, paper-based, and electronic data record-keeping systems are subject to the same requirements.[2] The acronym "ALCOA +" summarizes the data integrity requirements:

[2] Sarah Barkow & Karen Takahashi, Center for Drug Evaluation and Research, *Current Expectations and Guidance, Including Data Integrity and Compliance with CGMP* at 11 (Mar. 30, 2017), *available at* https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM561491.pdf.




40. The "+" in the acronym "ALCOA +" refers to the requirement that in addition to ALCOA, all data must also be complete, consistent, enduring, and available.

41. The FDA must necessarily rely on data generated and provided by Akorn and other pharmaceutical companies in making important public health decisions about both proposed new drugs and drugs currently on the market. A rigorous data integrity program is therefore required to ensure product safety and efficacy. The Agency has emphasized that "ensuring data integrity is an important component of [the pharmaceutical] industry's] responsibility to ensure the safety, efficacy, and quality of drugs, and FDA's ability to protect the public health."[3] If companies violate data integrity requirements, there can be no assurance that their testing data are complete, consistent, accurate and free from fraudulent or improper manipulation.

42. The FDA has emphasized that companies that violate data integrity requirements face severe sanctions. It has noted that it "rel[ies] on firm's[sic] to do the right thing when [the]

[3] cGMP FDA, Draft Guidance for Industry, Data Integrity and Compliance with CGMP at 1 (2016).

FDA is not present," and data integrity problems "break trust."[4] Once trust is lost, the FDA will not act on new drug applications in the normal course until the manufacturer has restored that trust with the FDA. This is invariably a difficult, time-consuming, and expensive process. Moreover, if the FDA were to find that Akorn failed to meet cGMP, the FDA could prevent it from manufacturing its approved products.

43. Another important aspect of a data integrity system is IT infrastructure. The FDA requires that computer systems have adequate "access controls" that computer systems have adequate "access controls" that restrict who may access electronic data, as well as "change controls" designed to "ensure that no unnecessary changes are made, that all changes are documented, and that the possible effect of a change is evaluated prior to its implementation." The FDA also requires that lab equipment have "audit trails" to document who uses the equipment, when, and for what purpose.

44. Data integrity also requires ensuring the authenticity of entries in laboratory notebooks. Notebooks contain original source data that should be contemporaneously recorded by chemists. Notebooks must be preserved, and missing notebooks are "an important data integrity issue" because "that data is no longer available" and cannot be verified. At Akorn, each notebook is assigned to a particular individual; making unsigned entries in another analyst's notebook violates fundamental principles of data integrity.

45. The FDA's data integrity rules require that all test data—both failing results and passing ones—be properly recorded. The FDA forbids the practice of "testing into compliance,"

[4] CAPT Sharon K. Pederson (Thoma), PharmD, National Expert of Pharmaceutical Inspections, FDA, Medical Products and Tobacco Program Operations Branch, Data Integrity Issues & Concerns at 29 (Feb. 6, 2017).

or running tests again and again until passing results are secured and recording only the passing results.

46. FDA regulations require that potential data integrity violations be promptly investigated and remediated. FDA guidance calls for "potential data falsification" to be "fully investigated" by the firm's "quality system to determine the effect of the event on patient safety, product quality, and data reliability; to determine the root cause; and to ensure the necessary corrective actions are taken."

### 3. The FDA's Inspection Regime

47. As part of the FDA's procedures to ensure compliance with cGMP and other requirements, FDA inspectors regularly inspect the Company's manufacturing and R&D facilities on a risk-based schedule. If the inspectors observe conditions that may violate the Food Drug and Cosmetic Act ("FD&C") or FDA regulations, they issue a Form 483, which is officially called a "Notice of Inspectional Observations." A Form 483 is issued at the end of an inspection if the FDA field investigator observed deficiencies quality control or violations of the FD&C. Companies may provide the FDA with written responses within 15 days. Such a response must identify a course of action to correct the conditions noted in the Form 483. A detailed response to each observation or violation noted is also required. If the FDA determines that the Form 483 response is inadequate, it may issue a formal Warning Letter detailing possible enforcement actions.

48. In addition, upon completion of the inspection, the FDA will categorize the results as: Official Action Indicated ("OAI"), Voluntary Action Indicated, or No Action Indicated. If the FDA categorizes an inspection as OAI, that "means FDA has some concerns with the conditions that they found during inspection. And it typically means that you will not get product approvals during that time frame."

49. When the FDA uncovers "a pattern or practice of wrongful conduct that raises a significant question about the reliability of data," the agency may invoke its "Application Integrity Policy" ("AIP").[5] Imposition of an AIP would suspend all of Akorn's drug applications until Akorn can demonstrate that its data is reliable and put in place a third-party monitor to oversee the Company's facilities.

50. Akorn explicitly told Fresenius in a November 2016 presentation while marketing the company that it was "[a]ligned with FDA guidance on data integrity."

**B. Akorn's Quality Control Systems**

51. Akorn purports to maintain an internal quality system which is implemented by its Quality Operations team and its Global Quality Compliance ("GQC") team. Quality Operations includes Akorn's quality system, which includes the quality assurance ("QA") and quality control ("QC") functions. GQC is responsible for reviewing FDA regulations and ensuring that its facilities are meeting FDA requirements by performing periodic internal audits and retaining third-party consultants.

52. Defendant Silverberg joined Akorn in April 2005 and beginning in May 2006 served as the Company's Executive Vice President of Global Quality Affairs. In this role, Mr. Silverberg was the most senior quality official at Akorn, reporting directly to Mr. Rai and overseeing more than 500 employees at the Company.

53. In this role, Silverberg placed "a lot of pressure" on employees "to just get things done and get products out [the] door."

[5] FDA, Application Integrity Policy, 1-1-6 (Mar. 4, 2004).

54. With Silverberg in this role, even as late as 2014, Akorn's internal audits were comprised of informal visits by individual inspectors. These visits, however, did not comport with industry norms and did not mimic full, site-wide FDA inspections, as required.

55. An employee survey in January 2016 that went to Defendant Rai and other members of senior management made the following comment:

> Our current Executive Vice President of Quality Assurance is not fostering a willingness to change the current Akorn culture. Instead of acknowledging and embracing our compliance gaps and working collaboratively with other groups to change and mature our quality systems, he actively works to prevent collaboration and transparency. He has actually counselled his staff to not speak to Global Quality Compliance staff and to not share information with GQC. This is not in line with our new mission and values statement. He has also provided misleading information to regulatory bodies including the US FDA.

This January 2016 comment was never investigated.

56. Nevertheless, by April 2016, Akorn's Board of Directors and Rai concluded that Silverberg was "not up to the task of carrying out his duties and needed to retire."

57. Despite this determination by the Board of Directors, it did not follow through on this determination, allowing Mr. Silverberg to continue at his post for another two years when he was finally removed a year after the Merger Agreement was executed.[6] Vice-Chancellor Laster's Order noted that "[a]fter constructively firing Silverberg, Akorn did not use the opportunity to deliver any type of message to its employees about the importance of data integrity or its intolerance for inaccurate submissions to the FDA."

58. In addition to Akorn's internal audit function, Akorn also retained "data integrity advisors" Cerulean Associates LLC ("Cerulean") in December 2016 and May 2017. Cerulean is a data integrity consulting firm that focuses on reviewing companies that "have problems."

[6] When Silverberg was finally removed, he was replaced by Kim Wasserkrug.

59. In 2016, Akorn performed a "gap" assessment at Akorn's manufacturing facilities in Decatur, Illinois and Somerset, New Jersey. These gap assessments were designed to determine whether Akorn was in compliance with federal regulations.

60. The principal of Cerulean, John Avellanet testified that Akorn was among the "top three worst" of the over 120 pharmaceutical companies that he had assessed and that Akorn's data integrity failures were so significant that he would not expect to see them "at a company that made Styrofoam cups." One of Akorn's board members described Cerulean's findings as "very damning."

## II. Akorn's Quality Control Systems Identify Major Data Integrity Problems

### A. Submission of False Data to the FDA

61. As explained above, Akorn's internal audit program did not comport with industry norms and did not mimic full, site-wide FDA inspections as they were supposed to.

62. In October 2012, a senior QC employee at Akorn's Somerset facility was asked to provide overdue stability testing data for an antibiotic named azithromycin. The senior QC employee said that the overdue data would take an additional month to prepare and his manager complained that this was unacceptable. Under pressure to quickly provide test results in connection with an ANDA for azithromycin, and without the technological capacity to complete this testing within the timeframe required of him, Somerset senior QC employee and lab supervisor Jim Burkett allegedly forged test results in a chemist's laboratory notebook. This allegedly fraudulent data was submitted to the FDA in December 21, 2012 as part of the ANDA for azithromycin.

63. An Executive Director of Quality at Akorn's Somerset facility allegedly identified these forged entries in November 2014. "By no later than early 2015, other Akorn employees — including a senior manager of QC and Quality Assurance ("QA") at Somerset and another QC

manager — knew that the data submitted to the FDA 'does not appear accurate.' Yet Akorn kept this secret and maintained the azithromycin application on file with the FDA."

64. In January 2015, Akorn received a Complete Response Letter ("CRL") from the FDA identifying issues with the azithromycin ANDA that were required to be addressed before the FDA would approve the ANDA. The CRL, among other things, requested additional test data.

65. While preparing its response to the CRL, Akorn's senior executives learned about the submission of forged test results to the FDA in 2012. For example, in July 2016, Defendant Silverberg, then Akorn's Executive Vice President for Global Quality Assurance, who reported directly to Defendant Rai, travelled to the Somerset facility where he spoke with the chemist whose notebook contained the forged entries. The chemist identified to him numerous entries that she did not make – not just for azithromycin, but also for six other products. The fraudulent entries even reported positive results for a test that could not have been performed at the Somerset site because of the absence of certain equipment. In addition, the chemist reported that two additional laboratory notebooks were missing.

66. Despite learning of the fraudulent submission of testing data to the FDA, Silverberg instructed the Somerset facility not to open a formal investigation and no formal investigation was conducted.[7] Indeed, according to Akorn's Head of Quality at Somerset, "'when I had pushed for an investigation on this issue, [Silverberg] had told me no.'"

67. Akorn allegedly has "concede[d] that there are forged notebook entries involving five other products, including three products for which such data was submitted to the FDA."

> Azithromycin: In December 2012, Akorn submitted fraudulent test results to the FDA in an ANDA for an antibiotic named azithromycin. Somerset lab supervisor Jim Burkert, when pressured to quickly provide test results for particulate matter (a measure of undissolved solids in the product), forged the

[7] FTB at 19.

> purported results in the lab notebook of another chemist. . . . The Somerset facility did not have the technology to conduct the test. Shortly thereafter, the fabricated data was submitted to the FDA in an ANDA on December 21, 2012. Although an Executive Director of Quality at Akorn's Somerset facility identified forged entries in notebooks as early as November 2014, there is no evidence that the forged entries were investigated.
>
> By mid-2016, senior Akorn quality executives, including Mark Silverberg, became aware of the forged entries. Silverberg instructed the Somerset site *not* to open a formal investigation. And no such investigation was conducted.
>
> * * *
>
> Olopatadine: Akorn generated yet more fraudulent test results in 2012 that were used in its ANDA filing for olopatadine (an eye medication). An employee at its Cranbury site generated positive stability testing results through inappropriate "testing into compliance," and that Akorn then submitted those results (but not the corresponding out-of-specification results) in an ANDA.
>
> Cyclopentolate: Akorn also generated fraudulent test results in 2013 that were used in its ANDA filing for cyclopentolate (another eye drug). An employee at Akorn's Vernon Hills site made a "deliberate change" in a testing procedure "to force a passing result[.]"

68. Thus, prior to entering into the Merger Agreement with Fresenius, Akorn allegedly submitted false or unsupported data to the FDA on at least three occasions.

**B. GQC Audit Reports**

69. In July 2015, the FDA identified a number of issues at Akorn's Amityville facility which led to a voluntary recall of several hundred thousand bottles of an antibiotic because of dissolution issues.[8]

70. Then, in early 2016, after reviewing the Somerset and Amityville facilities, a senior QA employee at Akorn's Decatur facility reported that "[a]ll labs seem to have issues with data that was aborted, invalidated, or otherwise not used for reporting is not reviewed or identified in

[8] https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=134599.

the data system." Akorn's senior management ignored these warnings, and management failed to take remedial actions in the ordinary course of business.

71. GQC's April 2016 internal audit of Akorn's Lake Forest facility found that audit trails were not being reviewed for "minimum criteria" such as "data manipulation" or "data deletion," despite the fact that "'multiple Akorn staff members' had unauthorized 'system access allowances,' which allowed them to modify and manipulate data and delete audit trails." An internal audit of Akorn's Somerset facility identified critical and "unmitigated" compliance risks related to data integrity.

72. Then, according to a June 2016 GQC audit report, Akorn's facility in Vernon Hills failed to establish appropriate computer access controls and audit trails – indeed, certain laboratory equipment was "unable to record audit trails" and could not identify the users performing tests. As a result of this failure, unauthorized personnel could "make changes in master production and control records." Akorn's Vice President of Quality Operations has opined that these problems "violate[] FDA guidelines." Like with the Lake Forest problems identified earlier in 2016, the GQC audit did not precipitate any remediation efforts and Vernon Hills still lacks any data integrity compliance plan.

73. More than a year after the FDA found numerous problems at the Amityville facility, in October 2016, GQC issued an audit report on Amityville identifying "critical" deficiency related to data integrity. According to GQC, unauthorized users could delete and override testing data, and important laboratory notebook entries were missing. In December 28, 2016, GQC issued another audit report of Akorn's Amityville facility. In this audit report, GQC found multiple problems directly related to issues the FDA had previously identified. For example, GQC found that the facility was out of compliance with 21 CFR 211.68(b), which states that "appropriate

controls shall be exercised over computer or related systems to assure those changes in master production and control records or other records are instituted only by authorized personnel." In addition, there was no instrument to record testing activity and no data backups had been performed on certain instruments. GQC marked this observation as "critical," and also reported four additional "major" violations. Thus, more than 14 months after the FDA's inspection, Akorn had ***still*** failed to remediate these critical data integrity problems.

74. None of these GQC audit findings were addressed or acted upon by the time that Akorn entered into the Merger Agreement with Fresenius.

**C. Cerulean Audit Report**

75. Cerulean issued a report on its assessment of the Decatur facility in December 2016. Cerulean identified seven "critical" findings that were "reasonably likely to directly impact the regulatory compliance status of the organization and/or product safety, efficacy or quality." The seven critical findings include:

- "Failure to exercise sufficient controls to prevent data loss."
- "Insufficient data integrity controls (both procedural and technical) to prevent unauthorized changes to electronic data."
- "Insufficient registered record archival controls and retention for records involved in drug product manufacture, testing and release, and quality records."
- "Failure to have sufficient controls over computerized equipment used in regulated processes and used to create, manipulate, edit, [and] store . . . regulated data for drug product safety and quality testing and release."
- "Inadequate validation of computerized systems to ensure the ongoing suitability of systems for Akorn processes, data, and personnel."
- "Inadequate control over approved specifications for drug product and raw materials, and failure to ensure that product testing data is derived from compliance with established specifications and standards."

- "Inadequate corrective action and preventative action and out-of-specification investigations, explanations, and corrective actions."

76. In addition to the critical findings, Cerulean found seven major findings and seven minor findings.

77. Cerulean concluded that "the data integrity controls at . . . Akorn's Decatur, Illinois site . . . are insufficient to support compliance with current data integrity expectations and US Food and Drug Administration (FDA) regulatory requirements. As a result, Akorn currently shoulders significant regulatory and negative public perception risk." Furthermore, the report warned that, "[r]epeat non-conformities . . . pose an increased risk because they are indicators that an organization did not take adequate corrective actions and thus may not treat its responsibilities as seriously as appropriate."

78. After reviewing Cerulean's "critical" findings related to access controls, Akorn's GQC internal audit team admitted that these findings were "valid" and "legitimate finding[s]." In fact, the head of data integrity at Decatur told Cerulean's principal that it was "pretty much exactly what we expected to see."

79. Nevertheless, Cerulean's findings were not acted upon by the time that the Company entered into the Merger Agreement with Fresenius.

**D. Senior Management Skips Training**

80. In order to comply with FDA requirements, it is important that employees are trained as to what those requirements are and how to comply.

81. However, by March 2017, it was clear that Akorn was not meeting these obligations. According to a March 2017 presentation to the Akorn Board Quality Committee, "[o]bservations revealed a systemic breakdown in Quality system across functions, which included

management responsibility, training, procedural deficiencies, qualification program weaknesses and 21 CFR Part 11 deficiencies."

82. Rather than actually conduct and attend trainings, Akorn instead created fraudulent records of trainings that it had conducted. For example, Akorn had claimed that it had devoted an outrageously high number of hours for employee trainings. Indeed, the hours claimed for the Decatur facility amounted to "7,000 trainings a month" which means that "assuming each individual works 7 days a week, with no vacations or sick leave, that's 232 trainings a day."

83. In stark contrast, when Cerulean was brought in to conduct a training at Vernon Hills covering, among other things, the importance of data integrity, no members of senior management attended.

**E. Senior Executives and the Board Are Notified of the Audit Reports**

**1. Reporting to Senior Executives**

84. According to Fresenius, "[a]ll of GQC's reports were distributed broadly to senior management" which would have included Defendants Rai and Portwood. Nevertheless, allegedly, "Rai neither took action nor asked if any follow-up actions had been taken" and "did not even read audit reports."

85. Indeed, Vice-Chancellor Laster concluded after trial that "Rai made claims about quality, but having considered his answers and evaluated his demeanor while he was being cross-examined about his commitment to quality, I am forced to conclude that he does not regard it as a priority." Even more alarming, is that the Vice-Chancellor concluded that he could also draw an inference that "Rai consciously disregarded Akorn's quality issues, including its data integrity problems":

> Another plausible and more alarming inference is that Rai consciously disregarded Akorn's quality issues, including its data integrity problems. Rai is the chair of Akorn's Quality Oversight Committee and its executive steering committee on data

> integrity remediation. He receives Akorn's internal audit reports, but he does not read them. Rai did not read the Cerulean reports either. After being asked about these documents at his deposition, he made no effort to familiarize himself with them between his deposition and trial. At his deposition, Rai could not recall whether he had ever seen the Decatur internal audit report that GQC sent him on March 23, 2018. When asked for Akorn's timetable to address the critical findings in the Cerulean report and March 2018 GQC report, Rai said he would "go back and ask" for one. Rai made that decision at his deposition and only because opposing counsel showed him the GQC report. At trial, Rai asserted that Akorn was "still assessing" a timetable for data remediation.

(citations omitted).

**2. Reporting to the Quality Oversight Committee**

86. The Company's quality and compliance departments, including GQC, were overseen by a committee of Akorn's Board, called the Akorn Board of Directors Quality Oversight Committee ("Quality Oversight Committee").

87. The audit reports detailed above were discussed at meetings of the Quality Oversight Committee. The members of the Quality Oversight Committee were aware of issues identified by the FDA and knew that failure to fix them would result in harm to the Company, and yet failed to ensure that these issues were appropriately addressed.

88. In 2014, Quality Oversight Committee minutes reflect that the committee was aware that the Company needed a "change of culture" around quality.

89. By June 2016, those issues had still not been addressed when Defendant Johnson, a member of the Quality Oversight Committee wrote to [Silverberg] regarding Akorn's culture of non-compliance for quality issues:

> I continue to be concerned that our position always seems to be that FDA got it wrong and we are just fine. I do not think we are fine, I think there are signals that we are missing. As the leader of the quality function, I do not understand how you can tolerate the continued non-compliance by employees, supervisors and quality assurance staff . . . . We have [dodged] a bullet a number of times, but at some point, our number will be up unless we, once and for all, fix the underlying reasons why our people do not adhere to procedures. Why do we not see an effort to do this?

90. Then, six-months later, during a Quality Oversight Committee meeting in December 2016, Defendant Johnson, again "expressed his concern around the repetitiveness of issues between sites and across sites identified during audits & external inspections" emphasizing need for "corrective actions on a global basis[,]" and director Brian Tambi noted that "it appears that the implementation of corrective action is lacking or not timely" Similarly, the Quality Oversight Committee found that internal audit "metrics [do] not clearly show[] if the corrective actions were actually implemented in a timely manner or not."

91. As admitted by Defendant Rai, by November 2016, he and the other Quality Oversight Committee members were "aware of significant and repeat problems that Akorn was having in its quality function" across all of Akorn's sites.

92. Nevertheless, neither Johnson nor Tambi, nor any other member of the Quality Oversight Committee actually took steps to ensure that these critical issues were actually addressed.

93. The members of the Quality Oversight Committee who received audit reports and were aware of serious data integrity and compliance problems by December 2016, included: Defendant Rai; Defendant Silverberg; Akorn's COO; Board Defendants Weinstein, Johnson and Tambi; and other top Akorn executives.

**F. Audit Committee**

94. The Audit Committee of Akorn's Board of Directors ("Audit Committee") was obligated to implement reporting systems, monitor those reporting systems, and to take steps to prevent or remedy violations of law that were identified by those reporting systems. These

obligations and others are detailed in the Audit Committee Charter.[9] Among other things, the Audit Committee is required to:

- Evaluate whether management is setting the appropriate "tone at the top" by communicating the importance of the Company's ethical and business practice standards.[10]
- Ensure that management has established a system to enforce the Company's Code of Ethics and review any requests for exceptions to the Company's Code of Ethics.[11]
- Review and discuss with management the Company's major risk exposures and the steps management has taken to monitor and control such exposures and safeguard the Company's assets.[12]
- Review and discuss with management, the internal audit department, and the independent auditor the Company's internal audit procedures.[13]
- Conduct or authorize investigations into matters within the Audit Committee's scope of responsibilities, as deemed necessary or appropriate by the Audit Committee.[14]
- Receive reports on legal compliance and litigation matters and review reports to management prepared by the internal auditors as well as management's responses thereto.[15]

[9] Akorn, Inc. Audit Committee Charter, *available at* http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Mzg0MzkwfENoaWxkSUQ9LTF8VHlwZT0z&t=1&cb=636367792777803026 ("Audit Committee Charter").

[10] Audit Committee Charter ¶ 13.

[11] Audit Committee Charter ¶ 25. The Code of Ethics provides that "[n]o employee should ever (i) destroy any Akorn documents in anticipation of a request for those documents from a government agency or a court, (ii) alter any Akorn documents or records, except as provided in corporate policy and procedures manuals (iii) lie or make any misleading statements to any government investigator, or (iv) attempt to improperly influence an employee or any other person not to provide information to any government investigator or to provide false or misleading information.

[12] Audit Committee Charter ¶ 15.

[13] Audit Committee Charter ¶ 16.

[14] Audit Committee Charter ¶ 33.

[15] Audit Committee Charter ¶ 32.

95. The GQC and Cerulean audit reports detailed above implicated several of these Audit Committee duties. For example, they identified: breakdowns in Akorn's internal audit procedures with respect to the falsified laboratory notebooks; major risk exposures as well as a failure to monitor or control those exposures; violations of the Company's Code of Ethics; and serious lapses in legal compliance.

96. The members of the Audit Committee who received audit reports and were aware of serious data integrity and compliance problems by December 2016, were: Defendants Abramowitz, Johnson, Meyer (Chair), and Rappuhn.

**G. The Board Is Aware of Recurrent Problems**

97. Among the duties of the Audit Committee, is to "[r]eport to the Board any illegal activity that it becomes aware of by or at the Company . . . ."[16]

98. Members of the Audit Committee (and the Quality Oversight Committee) knew of "critical" instances of non-compliance, "reasonably likely to directly impact," "product safety" and "regulatory compliance."

99. Because regulatory compliance failures are by definition "illegal" activities, it is presumed that the Audit Committee informed the full Board of the very serious problems to which it was alerted.

100. Indeed, as defined by the reports, "critical" findings were defined as those "reasonably likely to directly impact . . . the regulatory compliance status of an organization . . . and/or product safety, efficacy, or quality," and which "have consistently resulted in public enforcement activities (*e.g.*, FDA Warning Letter, product recall, etc.)[.]"

[16] Audit Committee Charter ¶ 28.

101. The members of the Board of Directors who were informed of illegal and serious data integrity failures by December 2016, included: Weinstein, Abramowitz, Graves, Johnson, Meyer, Rappuhn, and Tambi, as well as former director Kapoor.

102. Despite being aware of illegal and serious data integrity failures at Akorn, being aware that the Company needed a change in culture around quality issues, and that issues identified by internal and external auditors were not being addressed, each of the members of the Board and the Quality Oversight Committee failed in their duties to address these issues.

103. Indeed, once the Board became aware of the serious compliance issues at the Company, rather than focusing on remediation efforts, which may have negatively impacted the value of their stock holdings, the Board instead focused on trying to merge with another company – which would result in a significant windfall to the Director Defendants, while foisting the massive data integrity and compliance issues on the successor company.

104. For example, in the summer of 2016, Akorn met with representative from several potential strategic merger partners, and then on July 27, 2016, the Board commenced "a process to solicit proposals to acquire the Company from potential strategic and financial counterparties."[17]

### H. The Defendants Approve Two False and Misleading Proxy Statements in Order to Perpetuate the Unlawful Business Practices, Get Re-Elected, and Increase Their Compensation

#### 1. The False and Misleading 2016 Special Proxy Statement

105. On November 14, 2016, Defendants Rappuhn, Johnson, Kapoor, Abramowitz, Graves, Meyer, Tambi, and Weinstein reviewed, approved, and caused the Company to file a Proxy Statement for a special meeting of the shareholders (the "2016 Special Proxy"). The Proxy stated: "The Board of Directors (the "Board") of Akorn, Inc. (the "Company") is furnishing you

[17] Akorn, Inc., Schedule 14A at 26–27 (June 15, 2017) ("Merger Proxy").

this proxy statement to solicit proxies on its behalf to be voted at the 2016 special meeting of shareholders of Akorn, Inc. The special meeting will be held at the Company's headquarters, at 1925 West Field Court, Suite 300, Lake Forest, Illinois 60045, on December 16, 2016, at 10:00 a.m., local time."

106. The purpose of the special meeting of shareholders was to solicit shareholder approval for the following items, which all Directors urged shareholders to approve: (1) to approve the Akorn, Inc. 2016 Employee Stock Purchase Plan ("ESPP") (Proposal 1); and (2) to approve the amendment and restatement of the Akorn, Inc. 2014 Stock Option Plan (Proposal 2).

107. The purpose of the 2016 ESPP was to attract and incentivize employees and provide a means to compensate employees. The Proxy stated that "If approved by our shareholders, the 2016 ESPP will allow eligible employees to acquire shares of our common stock at a 15% discount."

108. With respect to Proposal 2 — the amendment of the 2014 Stock Option Plan – the Proxy stated: "The Amended 2014 Option Plan is intended to attract and retain exceptional directors, employees and consultants and to enable such individuals to participate in our long-term growth and financial success."

109. The Proxy stated that the type of securities authorized under the 2014 Stock Option Plan included Performance Units and Performance Shares. The Proxy further stated that: "Performance units and performance shares are awards that will result in a payment to a participant only if performance goals established by the administrator are achieved or the awards otherwise vest. The administrator will establish performance goals in its discretion, which, depending on the extent to which they are met, will determine the number and/or value of performance units and performance shares to be paid to the participant. The performance goals may be based upon the

achievement of company-wide, divisional or individual goals or objectives, or any other basis that the administrator determines."

110. The Proxy stated the following as to "New Plan Benefits" that would be established under the amended 2014 Stock Option Plan if the amendment were approved by shareholders:

> **New Plan Benefits**
>
> The number of awards that an employee, director, consultant or advisor may receive under the Amended 2014 Option Plan is in the discretion of the administrator. ***Upon approval of the Amended 2014 Option Plan, the following benefits or amounts will be allocated to the following individuals: Raj Rai, Chief Executive Officer, dollar target value of $824,000 (maximum value of $1,648,000).***

111. To convince shareholders to vote in favor of these two proposals, the 2016 Special Proxy Statement contained the following statement:

> **Compensation Philosophy and Objectives and Role of the Compensation Committee**
>
> Our compensation philosophy is based on the following goals and principles:
>
> - Motivate and reward a prudent level of risk and decision making in an effort to drive reasonable performance
> - Involve a limited use of perquisites and supplemental benefits which will only be provided if a compelling business rationale exists.

112. With respect to Defendant Raj Rai, who as noted *supra* was to be the recipient of the "New Plan Benefits" under the amended 2014 Stock Option Plan, the Proxy highlighted Rai's compensation in 2015 and stated that the Board determined the compensation was justified and earned by Rai based on Rai's alleged efforts in ensuring that Akorn complied with FDA rules and regulations:

**2015 Performance-Based Annual Incentive Award for our Chief Executive Officer**

For 2015, the Company achieved the following financial metrics: Sales of $985 million, Adjusted EBITDA of $460 million and Adjusted EPS of $2.02.

In addition to reviewing the Company's financial metrics, the Compensation Committee evaluated the Company's performance against key strategic initiatives designed to promote the Company's long-term success, as well as significant events during 2015. We continue to make progress on our plan to prepare Akorn India Private Limited (AIPL) for FDA certification. We submitted 18 ANDAs and 1 NDA to the FDA, and we launched 12 new products. We also have concentrated our efforts to enhance our culture and develop organizational talent.

**The Compensation Committee determined that Mr. Rai should be awarded an incentive bonus based on the following achievements in 2015**. Mr. Rai led the Company to deliver $985 million in sales and $151 million (GAAP) net earnings. Additionally, Mr. Rai provided the leadership and direction during the unstable restatement environment that enabled the company to have these business successes. He significantly strengthened the talent of the organization through the hiring of key executives across all functions. **He personally negotiated with lenders and regulatory agencies to ensure the Company maintained its ability to operate effectively.** ***Mr. Rai ensured that all of the Company's operations maintained regulatory compliance so that we could continue to manufacture, distribute and sell our products.***

113. The 2016 Special Proxy also identified the performance-based metrics set for 2016: "For the 2016 performance-based annual incentive plan, the following Company financial goals were set at Sales of $1.08 billion, Adjusted EBITDA of $499 million and Adjusted EPS of $2.15, as well as individual MBOs for each executive officer."

114. The 2016 Special Proxy also set forth Akorn's Clawback Policy:

**Clawback Policy**

In February 2016, the Company adopted a compensation clawback policy ("Clawback Policy") that applies to all executive officers and incentive-based compensation (including discretionary bonuses) awarded to such officers. **Under the policy, the Company may require the forfeiture and repayment of incentive-based compensation if** (1) the Company is required to prepare an accounting restatement due to material noncompliance with financial reporting requirements under the federal securities laws, **(2) an executive officer received incentive-based compensation based on materially inaccurate financial**

> **statements or materially inaccurately determined performance metrics, (3) an action or omission by an executive officer results in material financial or reputational harm to the Company**, or (4) an executive officer violated a non-compete or non-solicit provision or engaged in a felony or professional conduct injurious to the Company, its customers, employees, suppliers, or shareholders. **In any such event, the Compensation Committee may require that an executive officer forfeit or repay all or any portion of any outstanding unpaid incentive-based compensation that was awarded to the officers and any incentive-based compensation that was paid to the officers during the 36 months prior.** If a restatement occurs or an award is based on materially inaccurate financial statements or performance metrics, the Compensation Committee will consider all facts and circumstances that it determines relevant, including whether anyone responsible engaged in misconduct and issues of accountability.

115. The 2016 Special Proxy also disclosed that, because the Company had been forced to restate its financial results in 2015, some of the Company's executive officers had been forced to re-pay some of their incentive-based compensation earned during relevant time period. The Proxy stated:

> In light of our restatement, and as referenced in the Form 10-K/A filed in April 2015, in May 2016 the Compensation Committee re-evaluated the base, "stretch" and discretionary bonuses paid to the individuals listed as "named executive officers" for fiscal year 2014 (the "2014 NEOs"). Under our performance-based annual incentive plan in which the 2014 NEOs participated, if we do not achieve our Adjusted EBITDA target for a year, no awards are to be paid under the plan, even if other objectives were achieved. As a result of our restatement, it was determined that the Adjusted EBITDA that we actually achieved for 2014 did not meet the target threshold for that year. As a result, the Compensation Committee determined, and the Board approved, that the Company would seek repayment of 100% of the after-tax bonuses (base, "stretch" and discretionary) that were paid to each of the 2014 NEOs who are still employed by the Company for their service in 2014.

116. Given the past misconduct by Akorn's officers and directors relating to the Company's financial results, and the direct effect of such misconduct on incentive-based compensation, information about the Company's regulatory and legal compliance was of heightened interest to Akorn shareholders and should have been disclosed in the 2016 Special

Proxy, especially in light of the Board's request that shareholders vote to approve the 2016 ESPP and to approve the amendment and restatement of the Akorn, Inc. 2014 Stock Option Plan.

117. As detailed herein, the Board knew that the Company and its facilities were not in compliance with regulatory requirements concerning data integrity at the time the 2016 Special Proxy was issued, yet nevertheless disseminated the 2016 Proxy. As detailed herein, the Individual Defendants, at the time they approved the 2016 Special Proxy, had knowledge of Akorn's unlawful business plan and practices, which were fundamentally predicated on knowingly violating regulatory requirements and FDA regulations and which put the Company at material risk, and yet wrongfully failed to disclose this information to shareholders.

118. On December 16, 2016, Akorn's shareholders voted to approve the ESPP, including making 2 million shares of Akorn common stock available for issuance thereunder, and also voted to approve the Stock Option Plan.

119. The 2016 Special Proxy harmed Akorn by preventing the Company's shareholders from making an informed decision as to whether to approve the ESPP and the amendment to the Stock Option Plan - which provided additional compensation to the Company's officers on the basis of, among other things, purportedly effective compliance efforts. As a result of the false and misleading statements in the 2016 Proxy, Akorn's stockholders voted to approve the ESPP and the Stock Option Plan.

120. Had the Akorn shareholders been fully informed about the true operations at Akorn, including the blatant and pervasive regulatory and compliance violations, they would not have voted to approve the ESPP and the amendments to the Stock Option Plan. The adoption of the ESPP and the amendments to the Stock Option Plan helped to perpetuate the deceit and wrongdoing and violations of law at Akorn by providing additional compensation to key

executives at the Company, including Rai, which was tied to performance goals which were only being achieved as a result of the regulatory and compliance violations.

**2. The False and Misleading 2017 Annual Proxy Statement**

121. On March 20, 2017, Defendants Rappuhn, Johnson, Kapoor, Abramowitz, Graves, Meyer, Tambi, and Weinstein reviewed, approved, and caused the Company to file a Proxy Statement.

122. In the 2017 Annual Proxy Statement, the Directors all urged shareholders to vote in favor of the following proposals: (1) the re-election of the Directors; (2) the ratification of the appointment of the Company's auditor, BDO USA, LLP; (3) to approve the 2017 Omnibus Incentive Compensation Plan; and (4) to approve the Company's executive compensation program.

123. With respect to Risk Management, the Proxy stated:

> **Risk Management**
>
> We accept the premise that with innovation and progress we must also confront various risks. We also recognize that risk can be predicted, evaluated, avoided and/or managed. Further, ***the Board acknowledges that inappropriate risk avoidance and management could damage Company assets as well as shareholder value.*** Given these principles, senior management is responsible for assessing and managing the Company's various exposures to risk on a day-to-day basis, including the creation of appropriate risk management and compliance programs and policies. ***We have developed a consistent, systemic and integrated approach to risk management to help determine how best to identify, manage and mitigate significant risks throughout the Company. The Board is responsible for overseeing management in the execution of its responsibilities and for assessing the Company's approach to risk management***. The Board's role in risk oversight of the Company is consistent with the Company's leadership structure, with the CEO and other members of senior management having responsibility for assessing and managing the Company's risk exposure, and the Board providing guidance in these areas.

124. With respect to the role of the Directors on the Company's Audit Committee with respect to Risk Management, the Proxy stated:

> The Audit Committee oversees Akorn's financial reporting process on behalf of the Board. As part of this oversight function, ***the Audit Committee oversees Akorn's compliance with legal and regulatory compliance and monitors Akorn's compliance with Section 404 of the Sarbanes-Oxley Act of 2002, which includes receiving regular reports and representations by management and the Chief Audit Executive of Akorn and its independent auditors, each of whom is given full and unlimited access to the Audit Committee*** to discuss any matters which they believe should be brought to our attention.
>
> In carrying out its responsibilities, the Audit Committee acts in an oversight capacity. Management has the primary responsibility for the financial statements and the reporting process, including the system of internal controls.
>
> In this context, the Audit Committee has met and discussed the audited financial statements with management. Management represented to the Audit Committee that Akorn's consolidated financial statements were prepared in accordance with generally accepted accounting principles.
>
> The independent auditors reviewed with the Audit Committee the planning and scope of the audit of Akorn's consolidated financial statements and management's assessment of the effectiveness of internal control over financial reporting. The independent auditors regularly updated the Audit Committee regarding the audit status, as well as observations from their review of Akorn's quarterly consolidated financial statements. Members of the Audit Committee met privately with the independent auditors throughout the year regarding internal control over financial reporting matters and the status of remediation of material weaknesses.

125. With respect to Defendant Ronald Johnson, and in support of his re-election to the Board, the 2017 Annual Proxy stated:

> Among other qualifications, ***Mr. Johnson brings to Akorn's Board extensive experience in managing regulatory and compliance requirements of the FDA, particularly in pharmaceutical, medical device, biologic and biotechnology industries, as well as a deep knowledge and understanding of FDA policies and procedures*** regarding cGMP compliance, quality control processes and outcomes reporting gained from his years of providing specialized consulting services to governments, pharmaceutical companies and healthcare institutions and working at the FDA.

126. Moreover, the 2017 Annual Proxy also stated that the Company had completely remediated its internal controls and procedures to remedy defects which had previously resulted

in the need to restate its financial results, and that the Company's internal controls were fully functioning, effective, and adequate. The 2017 Annual Proxy stated:

> In addition, ***under the current Audit Committee, the Company has strengthened its risk assessment process by establishing mechanisms to identify, evaluate and monitor risks to financial reporting. Further, the Company has updated its global risk assessment process, evaluation, and mitigation strategies, and strengthened its internal audit plan to include internal audit monitoring of these activities. The Company has also implemented new procedures and enhanced controls governing its internal management-led Disclosure Committee, sub-certification and external reporting processes associated with the review and approval of the content of its SEC filings and other public disclosures***. ***Further, the Company has implemented controls to prevent or detect material errors in the financial statements of acquired subsidiaries***. These controls consist of a comprehensive merger and acquisition integration approach, timely assessment of the target's control environment, and a process to facilitate improvements in the subsidiary's control environment within the year of acquisition.

127. The 2017 Annual Proxy also stated:

> • CODE OF ETHICS
>
> Our Board has adopted a Code of Ethics that is applicable to all employees, including our principal executive officer, principal financial officer, principal accounting officer, controller and persons performing similar functions, as well as members of the Board. We intend to satisfy any disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, any provision of the Code of Ethics with respect to our principal executive officer, principal financial officer, principal accounting officer, controller and persons performing similar functions by disclosing the nature of such amendment or waiver on our website or in a report on Form 8-K. A copy of the Code of Ethics can be obtained at our website.

128. The above statements conveyed that the Board (i) maintained sufficient compliance, risk controls, review, and reporting programs to identify and address deficiencies in Akorn's regulatory compliance; (ii) was unaware of existing material risks that could affect the Company; and (iii) maintained an "consistent, systemic and integrated approach to risk management to help determine how best to identify, manage

and mitigate significant risks throughout the Company."

129. The 2017 Annual Proxy also contained a detailed discussion of Defendant Rai's incentive-based compensation and stated that the level of compensation awarded to Rai was justified and earned based on, among other things, Rai's alleged success in ensuring Akorn's compliance with regulatory requirements:

> **2016 Performance-Based Annual Incentive Award for our Chief Executive Officer**
>
> For 2016, the Company achieved the following financial metrics: Sales of $1,117 million, Adjusted EBITDA of $509 million and Adjusted EPS of $2.25 . . .
> . . .
> ***The Compensation Committee determined that Mr. Rai should be awarded incentive bonus based on the following achievements in 2016***. He led the Company in achieving record revenues, surpassing a billion dollars. Under his leadership the Company exceeded all of its financial targets. The restatement of the 2014 financial statements and remediation of all of the earlier identified material weaknesses were significant accomplishments. ***Mr. Rai ensured that all of the Company's operations maintained regulatory compliance and we had significant progress in our plans to obtain FDA certification of our AIPL facilities. Additionally he continued to lead the building of our organizational talent and embedding of our culture***.

130. The 2017 Annual Proxy also represented that incentive-based compensation paid by Akorn to the Company's other executive officers, including Defendant Portwood, was merited based on their contributions to the success of the Company's objectives and goals, one of which was compliance with applicable rules and regulations, especially those related to the FDA. With respect to Mr. Portwood's incentive-based compensation for 2016, the Proxy stated:

> **The Compensation Committee determined that Mr. Portwood should be awarded an incentive bonus based on the following achievements**. Mr. Portwood led the Company's finance organization in restating the Company's 2014 financial statements and filing of the Company's 2014 and 2015 financial reports in a timely manner and to the satisfaction of the regulatory authorities and the Company's auditor. Additionally, ***the Company remediated all of the previously identified material weaknesses. Mr. Portwood led the continued development and growth of the Company's finance organization which has improved business processes***.

131. The 2017 Proxy omitted any disclosures regarding (i) "significant and repeat problems that Akorn was having in its quality function" across all of Akorn's sites; and (ii) "critical" instances of non-compliance, "reasonably likely to directly impact," "product safety" and "regulatory compliance." As detailed herein, the Individual Defendants, at the time they approved the 2017 Proxy, had knowledge of Akorn's unlawful business plan and practices, which were fundamentally predicated on knowingly violating regulatory requirements and FDA regulations and which put the Company at material

risk, and yet wrongfully failed to disclose this information to shareholders.

132. On April 27, 2017, Akorn's shareholders voted to approve each of the proposals in the 2017 Proxy.

133. The 2017 Proxy harmed Akorn by interfering with its shareholders' right to cast a fully informed vote regarding critical governance issues affecting Akorn. As a result of the false or misleading statements in the 2017 Proxy, Akorn stockholders voted to re-elect Defendants Kapoor, Abramowitz, Graves, Johnson, Meyer, Rappuhn, Tambi, and Weinstein to the Board.

134. The 2017 Proxy also urged stockholders to approve an advisory resolution regarding compensation paid to named executives. In support of the requested approval, in addition to the statements quoted above, the 2017 Proxy said:

> • Consistent with our ongoing goal to keep the Company's key executives' objectives and incentive pay aligned with the goals of our shareholders, we continue to pursue a compensation philosophy that is intended to provide total compensation opportunities, which include base salary, performance-based cash bonus, long term equity compensation, and a health and welfare benefits package. These are intended to incentivize the uniquely skilled employees who will continue to carry out our strategic plan, mission and goals, while maintaining our required high-quality standards and growth.[18]

[18] 2017 Proxy at 34.

- Our compensation philosophy is based on the following goals and principles:
    - Focus attention on and appropriately balance current priorities and the longer-term strategy of the Company through short- and long-term incentives,
    - Encourage teamwork and cooperation while recognizing individual contributions by linking variable compensation to Company and individual performance based on position responsibilities and ability to influence financial and organizational results, [and]
    - Motivate and reward a prudent level of risk and decision making in an effort to drive reasonable performance[.]

135. Those statements in the 2017 Annual Proxy conveyed the impression that Akorn's compensation system encouraged proper risk management and advanced long-term stockholder value. In reality, Akorn's compensation system actually encouraged-and consistently rewarded-extreme risk-taking and widespread illegal practices. Defendants knew or should have known the executives had breached their fiduciary duties to the Company by ignoring critical regulatory and data integrity violations while exposing the Company to significant and material risks and liability through their conduct related to data integrity and regulatory compliance.

136. As a result of the false and misleading statements in the 2017 Proxy, Akorn's stockholders voted to approve the proposals in the 2017 Proxy. Had the Akorn shareholders been fully informed about the true operations at Akorn, including the blatant and pervasive regulatory and compliance violations, they would not have voted to re-elect the directors, would not have voted to ratify the appointment of the Company's auditor, BDO USA, LLP, would not have voted to approve the 2017 Omnibus Incentive Compensation Plan, and would not have voted to approve the Company's executive compensation program.

## III. Negotiation and Execution of the Merger Agreement

### A. Fresenius and Akorn Negotiate and Execute a Merger

137. On October 13, 2016, Raj Rai, CEO of Akorn, and J.P. Morgan met in person with John Ducker, President and Chief Executive Officer of Fresenius Kabi USA, LLC ("Fresenius

Kabi USA"), a wholly-owned subsidiary of Fresenius Kabi, to give Ducker a presentation regarding Akorn's business and operations.

138. Throughout November 2016, Akorn and Fresenius discussed Akorn's business and operations, culminating in Fresenius's November 23, 2016, submission a nonbinding indication of interest proposing to acquire Akorn.

139. Negotiations between Akorn and Fresenius continued through February 2017, when Fresenius began conducting due diligence on Akorn.

140. On March 23, 2017, Fresenius Kabi submitted a revised nonbinding indication of interest proposing to acquire Akorn for a price of $33.00 per Akorn common share. In the indication of interest, Fresenius stated that it had largely completed its due diligence of Akorn, but that Akorn would have to provide additional information. Fresenius also stated in the indication of interest that it was prepared to commence negotiation of a merger agreement.

141. On April 2, 2017, Fresenius expressed a willingness to pay $34.00 per Akorn common share.

142. On April 7, 2017, Akorn shares opened trading at $25.45 per share as rumors began swirling concerning a potential merger. After the market close, Akorn confirmed that it was in discussions with Fresenius concerning a potential acquisition. By the close of the next trading day, Akorn's shares were trading at $32.50 per share.

143. Despite knowing about serious and ongoing compliance and data integrity issues at the Company, neither Rai, nor anyone else at Akorn ever disclosed any of these problems to Fresenius. This was a breach of their fiduciary duties to the Company.

144. Fresenius and Akorn signed the Merger Agreement and Plan of Merger ("Merger Agreement") on April 24, 2017. The Merger Agreement contemplated that Fresenius would

acquire all of Akorn's issued and outstanding shares for a cash payment totaling $34 per share ("Transaction").

**B. Akorn Was in Violation of the Merger Agreement When It Was Signed**

145. The Merger Agreement included a number of representations and warranties by Akorn. Akorn's representations regarding compliance with FDA rules and regulations and current Good Manufacturing Practices were particularly detailed. Occupying more than two single-spaced pages of the Merger Agreement, they include representations that Akorn was complying with "all applicable Laws (including all rules, regulations, guidance and policies) relating to or promulgated by" the FDA,[19] "current good manufacturing practices" and "standard medical and scientific research procedures,"[20] and that Akorn had not misled the FDA.[21] The Merger Agreement was signed by Defendant Rai and was reviewed and approved by Akorn's Board.

146. Under the Merger Agreement, the closing of the Transaction was expressly conditioned on Akorn's representations and warranties being correct "as of the date [of the Merger Agreement] and as of the Closing Date."[22] The only exception is "where the failure to be true and correct would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect."[23] A Material Adverse Effect is defined as having a "material adverse effect on the business, results of operations or financial condition of the Company."[24]

[19] Merger Agreement § 3.18(a)(1)(A).

[20] *Id.* §§ 3.18(b), (c).

[21] *Id.* §§ 3.18(d), (g).

[22] *Id.* §6.02(a).

[23] *Id.*

[24] *Id.* § 8.12.

147. The closing of the Transaction was also conditioned on Akorn's compliance in all material respects with its covenants in the Agreement,[25] including covenants to "carry on its business in all material respects in the ordinary course of business"[26] and to provide Fresenius with "reasonable access" to information about Akorn's business.[27]

148. As detailed in paragraphs 51 - 104 above, Akorn had significant, systemic, unresolved data integrity failures at the time it entered into the Merger Agreement, all of which were known by senior management and/or the Board. As a result, according to Fresenius, "Akorn's representations in the Merger Agreement were false even when that agreement was signed because of the extensive data integrity failures discussed above."

149. The Individual Defendants' conduct in causing Akorn to enter into the Merger Agreement while senior management and/or the Board knew that the Company was already violating the Merger Agreement constituted a breach of fiduciary duty. For example, Akorn falsely represented that since July 1, 2013:

- It had complied with all applicable Laws including FDA regulations;[28]
- All documents filed with the FDA were correct;[29]
- It had complied with cGMP;[30]
- All testing was in compliance with standard scientific procedures;[31]

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[25] *Id.* § 6.02(b).

[26] *Id.* § 5.01(a)(1).

[27] *Id.* § 5.05.

[28] Merger Agreement § 3.18(a)(1)(A).

[29] *Id.* § 3.18(b).

[30] *Id.* § 3.18(b)

[31] *Id.* § 3.18(c).

- It had not made an untrue statement or omission of material fact to the FDA;[32] and
- All ANDAs were materially accurate.[33]

150. Defendants Abramowitz, Johnson, Meyer, and Rappuhn agreed to execute the Merger Agreement despite having actual knowledge (by virtue of their receiving audit reports as members of the Audit Committee) that the representations therein were false. This was a breach of their fiduciary duties.

151. Also, Defendants Rai, Portwood, Weinstein, Johnson, and Tambi approved the Merger Agreement, despite having actual knowledge by virtue of their receiving audit reports as members of the Quality Oversight Committee that the representations therein were false. This was a breach of their fiduciary duties.

152. Finally, the other members of the Board, Defendants Graves and Kapoor, were notified by the members of the Audit Committee of the "critical" data integrity violations amounting to violations of law, and therefore knowingly agreed to execute the Merger Agreement, despite having actual knowledge that the representations therein were false.

## IV. Following the Execution of the Merger Agreement, Akorn Learns of Additional Regulatory Violations, Deceives Regulators, and Avoids Addressing Data Integrity Failings

153. Akorn's CEO, Defendant Rai allegedly acknowledged that Akorn was obligated to operate its business in the ordinary course until the merger was closed. This necessarily required the Company to investigate and then address any identified data integrity violations.

### A. Cerulean Issues an Audit Report Warning of Possible Criminal Liability

[32] *Id.* § 3.18(d).

[33] *Id.* § 3.18(g).

154. Cerulean issued its audit report on the Somerset facility in May 2017, which identified additional "critical" and "major" findings. This report concluded that some violations were so severe that Akorn's senior management should be concerned about potential criminal liability.

155. Notably, Akorn's senior management and IT failures were so serious that Cerulean "was unable to complete a full assessment of" Akorn's data integrity issues, ultimately finding the data integrity failures at Somerset were "so serious that it felt the need to alert Akorn's officers to potential *criminal liability* under the Federal Food, Drug, and Cosmetics Act."

156. Cerulean's report found that senior management failed to "ensure an effective quality system" and that the IT department did not "ensure the reliability of the controls around data used to make, test [and release] sterile drug products, which "raises serious concerns about the reliability of any data integrity controls and thus the trustworthiness of any electronic information used through Akorn to make safety, efficacy and quality decisions." Some of the critical findings identified by Cerulean at the Somerset facility included:

- Akorn's "[f]ailure to have sufficient controls over computerized systems . . . used to create, manipulate, edit, [and] store" data used for product testing; and
- "Audit trails appear to be inconsistently reviewed . . . ."

157. In describing Cerulean's audit report, its principal explained that it "literally calls into question every released product they've done for however many years it's been this way." He further explained that this "raises serious questions about the reliability of any data integrity controls and thus the trustworthiness of any electronic information used throughout Akorn to make safety, efficacy and quality decisions."

158. Cerulean also found that a critical deficiency at Somerset was the "[f]ailure of senior management with executive responsibility to ensure an effective quality system" was implemented and maintained throughout Akorn.

159. Given the seriousness of Cerulean's Somerset audit report, the Quality Oversight Committee would have discussed this report. The members of the Quality Oversight Committee who received Cerulean's May 2017 audit report and were therefore aware of potential criminal liability resulting from data integrity and compliance violations, included: Defendant Rai; Defendant Silverberg; Akorn's COO; Board Defendants Weinstein, Johnson and Tambi; and other top Akorn executives. Nevertheless, by March 2018, the GQC team found that Akorn had still not addressed the vast majority of the deficiencies. This represented a breach of fiduciary duty by the members of the Quality Oversight Committee.

160. Also, given the seriousness of Cerulean's Somerset audit report, the Audit Committee would have discussed this report. The members of the Audit Committee who received Cerulean's May 2017 audit report and were therefore aware of potential criminal liability resulting from data integrity and compliance violations, were: Defendants Abramowitz, Johnson, Meyer (Chair), and Rappuhn. Nevertheless, by March 2018, the GQC team found that Akorn had still not addressed the vast majority of the deficiencies. This was a breach of their fiduciary duties.

161. Finally, Defendants Graves and Kapoor, as Board members, were notified by the members of the Audit Committee of Cerulean's May 2017 audit report and were therefore aware of potential criminal liability resulting from data integrity and compliance violations. Nevertheless, by March 2018, the GQC team found that Akorn had still not addressed the vast majority of the deficiencies. This was a breach of their fiduciary duties.

162. Shockingly, despite learning of these failures, Akorn utterly failed to address them. "Of the 17 action items in Akorn's purported remediation plan scheduled to be completed by the third quarter of 2017, only three had actually been completed."

**B. Akorn Again Submits False Data to the FDA**

163. As alleged above, in 2015, Akorn received a Complete Response Letter from the FDA concerning its azithromycin ANDA.

164. Since the time that Akorn had submitted its azithromycin ANDA, Akorn had allegedly sent its azithromycin product to an outside laboratory for testing – and the outside laboratory determined that it had failed stability tests. Nevertheless, a senior QC employee allegedly again created fraudulent data indicating that the product had passed the stability testing. The falsified data was allegedly included in Akorn's draft response to the CRL.

165. Prior to submitting Akorn's response to the CRL, in August 2017, a senior manager of QA and QC at Somerset determined that the stability data had been falsified in Akorn's draft submission. The senior manager and the Executive Director of Quality at Somerset told Silverberg, Akorn's head of Quality Assurance, that the draft response to the CRL, if submitted, would contain fabricated data and urged Silverberg that the original ANDA should be withdrawn. Nevertheless, on August 31, 2017, Silverberg submitted the allegedly fraudulent data to the FDA as part of Akorn's response to the CRL.

166. Silverberg even executed a "sign off sheet" falsely stating that the CRL response "accurately represent[ed] the technical details to support this ANDA submission." Silverberg also took no action to withdraw the original ANDA submission for azithromycin containing fraudulent data.

167. Silverberg was in a position to take these actions because the Board failed to remove him from his position even after determining that he was "not up to the task of carrying

out his duties and needed to retire." The Board's failure to remove Silverberg directly resulted in the Company submitting false data to the FDA.

168. Akorn, when it learned about Silverberg's alleged fraud and his attempts to cover it up by February 2018, for months did nothing. Silverberg maintained his title and responsibilities until January or February of 2018, then moved him to the role of "Quality Advisor" and entered into an agreement with him "not [to] have any contact with [the] U.S. FDA or other regulatory authorities."

### C. Akorn Cancels External Audits, Limits Internal Audits, Suspends Its Board Level Compliance Oversight, and "Freezes" Data Integrity Projects

169. The Merger Agreement required that Akorn continue to operate in the normal ordinary course of business, following the signing of the Merger Agreement and until the date the merger was to take effect.[34] Nevertheless, in breach of the Merger Agreement, the Company allegedly directed employees not to work on data integrity projects.

170. Moreover, as detailed above, by December 2016, the Board was aware of "critical" compliance issues. By mid-2017, the Board was aware that Akorn's illegal conduct was significant enough to warn of ***potential criminal liability***.

171. Instead of operating in the ordinary course, Akorn changed how its quality function and IT function approached their jobs. Employees in these groups were told that "[p]riorities have been revised, and some 2017 initiatives will be stopped[,]" with the cited reason being the "implications of the pending Fresenius Kabi transaction."

172. Moreover, the Board and senior management pursued a strategy of: cancelling planned external audits to avoid learning of additional violations; limiting the internal audit function (GQC) to evaluating already identified compliance problems; freezing data integrity

[34] Merger Agreement § 5.01(a)(i).

remediation efforts; and suspending its Board level oversight of compliance and quality issues. These decisions constituted additional breaches of their fiduciary duties.

**1. Akorn Cancels Audits**

173. As detailed above, Cerulean issued an audit report on Akorn's Somerset facility in May 2017. However, it had been unable to complete the audit because Akorn's IT department refused to participate. While Akorn initially agreed to reschedule the rest of the audit, it never followed through or otherwise attempted to reschedule it.

174. Defendant Silverberg similarly cancelled a planned audit of the Amityville facility in May 2017, which was also never rescheduled.

175. These decisions were allegedly made "at the corporate level."

**2. Akorn Limits Its Internal Audit Function**

176. In addition to cancelling the audits in progress and scheduled with Cerulean, Akorn also put severe limits on its internal audit program. For example, in 2017, Akorn's GQC team began performing what it called "verification" audits – focused only on tracking the Company's progress on addressing prior audit findings rather than new violations and deficiencies. This was the first time that the Company performed such "verification" audits.

177. Despite dialing-back the audits to "verification" audits, they nevertheless found ongoing "unmitigated" compliance risks associated with Data Integrity and that Akorn had violated a commitment to the FDA to remediate certain data integrity issues.

178. More than a year after the Decatur audit report and ten months after the Somerset audit report, in March 2018, GQC conducted an audit "to determine the current state of the actions taken" to respond to Cerulean's findings with regard to Decatur and Somerset.

179. The GQC audit report of Decatur facility that examined whether Cerulean's December 2016 findings had been addressed, found that Akorn "failed to appropriately investigate

and remediate in a timely manner previously identified Data Integrity non-compliances" and had only "completed 32% of the corrective actions" thus far."

180. In April 2017, GQC audited Akorn's Somerset facility. This audit, like the Vernon Hills audit, identified problems with respect to improper access controls and audit trail reviews. Akorn had not remedied these problems by December 2017 – and like the Vernon Hills facility, Somerset still has no approved data integrity compliance plan.

181. GQC's audit of Akorn's response to the Somerset audit report found "no actions were taken in response" to the Cerulean audit report. According to GQC, "Somerset . . . while having received the draft audit report on 31 May 2017, decided to wait for the final report received on 3 March 2018 and failed to initiate formal corrective actions or have a documented plan to date."[35] Indeed, according to Wasserkrug, "in 2017, after getting the Somerset Cerulean report, no actions were taken in response."

182. By September 11, 2017, a second GQC audit of the Vernon Hills facility found that Akorn had still failed to address the previously identified issues, because corrective actions had "been halted and remain incomplete" and that these "***ongoing delay[s] in resolving the data integrity items presents undue risk to the site's ongoing operations.***"

183. According to Akorn's Vice President of Quality Operations, Kim Wasserkrug, Vernon Hills still does not have a data integrity compliance plan at all.

184. Similarly, GQC found in December 2017 that Akorn had not addressed the problems it had previously identified in April 2016 at Akorn's Lake Forest site.

185. Other 2017 GQC audits identified other data integrity deficiencies. In 2017 alone, 27 data integrity deficiencies were identified at Hettlingen, Switzerland, 15 data integrity

[35] FPTB at 24.

deficiencies at Cranbury, New Jersey, 5 data integrity deficiencies at Amityville, New York, and 5 data integrity deficiencies at Lake Forest, Illinois.

186. The Company's CEO, Defendant Rai was unable to provide a timetable for even addressing Akorn's outstanding "critical" issues. Indeed, according to Akorn's Data Integrity Quality Manager, Akorn was "making 0 progress on our DI remediation efforts," which she attributed to "the culture and the message from management."

**3. "Freeze" of Data Integrity Remediation**

187. For example, in May 2017, Akorn's leadership allegedly decided "that IT resources would not be engaged in the third party [Cerulean] data integrity audit." Later, in August 2017, Akorn's head of IT informed senior managers that that it was "not appropriate" to establish plans to address the "critical" data integrity violations."

188. Consistent with this message, the Executive Director of R&D Quality allegedly wrote in August 2017 that "[e]xecutive leadership have discussed and aligned that data integrity changes are not actionable in 2017[.]"

189. Also in August 2017, Somerset's head of quality told Silverberg that she "fully underst[ood] that we are on the cusp of the FK" merger, but that Somerset was "in a state of jeopardy as it relates to data integrity" and yet IT had determined that a serious system access problem did "not warrant" a review.

190. In December 2017, Akorn's Data Integrity Quality Manager, was reminded that "[b]ased on a previous executive leadership directive, data integrity is not a 2017 approved project" and that "DI remediation activities are not something that we are resourced to address at the moment."

191. As late as February 2018, Pramik was reminded to draft an email from "executive leadership . . . to align *all sites* that we are *not* launching data integrity remediation initiatives at the sites at this time." Pramik later described "DI related" projects as being "paused" or "delayed."

192. Indeed, Akorn's Project Review Board, a group of executives who allocated IT resources, even rejected an IT-related data integrity project.

#### 4. Suspension of Board Level Compliance Oversight

193. While reducing its audit function, Akorn's Board also made sure there was no one to receive the findings. In June 2017, Akorn suspended meetings of the Quality Oversight Committee – the body charged with overseeing compliance and addressing audit findings.

194. The decision to suspend the Quality Oversight Committee is one that could only have been made by the Board of Directors, and which constituted a breach of fiduciary duty in light of the serious problems known by each member of the Board at that time.

### D. Fresenius Receives Three Whistleblower Letters and Initiates an Investigation

195. In early October 2017, "Fresenius received a short, anonymous letter claiming that Akorn's research and development activities were significantly 'flawed and . . . mostly corrupted or incomplete.' Fresenius determined that the letter was not sufficiently detailed to justify a formal investigation at that time."

196. In November 2017, Fresenius received "[a] second and more detailed letter" that "provided detail about Akorn's 'corrupted' product development, including how Akorn senior executives (among them its CEO) pressured Akorn's Quality and Manufacturing Departments to 'manipulate or modify' data 'using pressure tactics and threats.' The letter described how, as a result, 'multiple data manipulations' had occurred at Akorn's Decatur, Somerset and Vernon Hills sites. The letter noted, in particular, that stability testing at Somerset had not been performed consistently. Stability testing is a type of testing that pharmaceutical companies must perform over time to demonstrate and ensure that their product does not excessively degrade, and this testing is required by the FDA in ANDAs seeking approval for new products."

197. When Fresenius received the second letter, Fresenius provided copies of both letters to Akorn, requesting that it open an investigation. In mid-November 2017, Fresenius and Akorn each allegedly began separate investigations.

198. According to the Opinion:

> After receiving the whistleblower letters from Fresenius, Akorn shared them with its board members. Johnson, a director with substantial FDA experience, described them as "very worrisome," noting that "[i]f they were to get to FDA, we should expect an intensive investigation" and that "[m]ost data integrity issues are surfaced through whistleblowers going to FDA." He advised that Akorn needed to conduct a "responsive and credible" investigation that "would require a review of named applications including product development files and lab notebooks" as well as "[i]nterviews of those involved, in any way, with the named submissions . . . ." He advised that if the investigation uncovered problems, then "a much broader investigation following FDA guidance would be necessary."

199. Then, "[i]n early January 2018, Fresenius received a third whistleblower letter raising more issues about Akorn and the integrity of its data. Fresenius promptly provided this letter to Akorn also."

200. Fresenius's and Akorn's investigations allegedly uncovered serious data integrity deficiencies.

201. For its investigation, Fresenius engaged Sidley Austin LLP (retained for its expertise in FDA regulations and compliance) and Lachman Consulting Services (a consulting firm with expertise in data integrity).

202. While Akorn ostensibly engaged Cravath, Swaine & Moore LLP, its deal counsel, and NSF Health Sciences to perform its investigation, "as it turned out, Akorn decided not to conduct its own investigation into the whistleblower letters because Akorn did not want to uncover anything that would jeopardize the Merger."

**1. The Lachman / Sidley Investigation**

203. In December 2017 and January 2018, Lachman identified similar issues at all of the sites that it visited. "Lachman conducted onsite assessments of Akorn's Vernon Hills, Somerset, and Decatur sites, and identified 'major, systemic data integrity gaps' at all three sites." Similarly, Lachman's team leader, "who has over 40 years of experience in the pharmaceutical industry and

has conducted many data integrity audits, described Akorn as having 'one of the poorest states of compliance that I have encountered.'" Lachman's specific findings included, for example:

- "[D]ata were not documented contemporaneously."
- Akorn improperly relied on "retesting" instead of adequately investigating failing tests, contrary to FDA guidance.
- Computer systems and lab software were "not secure from unauthorized change."
- "Electronic records were not traceable to a corresponding notebook entry."
- "Discrepancies were found" between data used to support ANDAs and the underlying notebooks.

204. According to Fresenius, "Lachman determined that these deficiencies 'call[] into serious question' the reliability of Akorn's testing data, the effectiveness of its quality system, the accuracy of its regulatory submissions, 'and thus the safety and efficacy of Akorn's products.'"

**2. The NSF / Cravath Investigation**

205. For Akorn's part, according to Akorn's CEO, rather than investigating the allegations of serious data integrity issues, Akorn "did not need to go do . . . our own investigation" and instead Akorn would simply "support" Fresenius's investigation. Indeed, even after learning about specific frauds by Burkett and Silverberg, the Company's General Counsel allegedly instructed that Akorn's advisors limit their investigation to those frauds, rather than undertaking a comprehensive review.

206. This failure to investigate allegedly violated the FDA's Draft Guidance for Industry on Data Integrity and Compliance with cGMP, which required Akorn's alleged data integrity violations to be "fully investigated under the cGMP quality system" to determine the effects on patient safety, product quality, and data reliability, and the root causes.

207. Instead of a full investigation, Akorn commissioned a limited investigation, and for that investigation hired counsel that, according to his own testimony, had never previously conducted an investigation into data integrity issues at a pharmaceutical company and had no familiarity with the FDA's regulations and guidance on data integrity.

208. Meanwhile, GQC, which should have taken a lead role under the FDA's guidelines, was assigned the very narrow task of "answer[ing] only . . . very specific questions," and was "not to follow additional threads/items."

209. Despite their very limited mandate, the investigators hired by Akorn found egregious violations of FDA rules.

210. The "investigation" by Cravath took approximately four weeks. Vice-Chancellor Laster found that the record supported the following findings:

- In 2012, Akorn began developing a topical ophthalmic form of azithromycin, a prescription antibiotic, at its Somerset site, but could not perform particulate matter stability testing due to its viscosity.

- In September 2012, an Akorn lab supervisor at Somerset named Jim Burkert entered stability testing data into the lab notebook of an Akorn chemist. There is no evidence that he had the data; he seems to have made it up.

- In December 2012, Akorn submitted to the FDA an ANDA for azithromycin which included the false data.

- In fall 2014, the stability testing issue came up again, and the same Akorn chemist discovered the entries in her notebook. She also noticed other entries in the same notebook and in two other notebooks that were not in her handwriting. She reported it to Burkert, who did not ask any questions or follow up. The chemist next brought the issue to the attention of a quality manager who instructed all scientists to review their notebooks. The review discovered numerous instances of altered and missing data. In addition, two of Burkert's notebooks were missing.

- On December 30, 2014, Burkert resigned voluntarily.

- In July 2016, Silverberg visited Somerset. He interviewed the chemist and told her to note in her notebooks where the writing was not hers. She identified six additional products where the writing was not hers. After

learning about the missing notebooks, Silverberg instructed that going forward, all notebooks would be stored in the quality manager's office and checked in and out. Employees expressed concern that Silverberg was not addressing the issues properly.

- In August 2017, Somerset was attempting to respond to a CRL that asked questions about the stability testing for azithromycin, albeit not specifically the fabricated test. When preparing the response, Akorn personnel identified the problems with the data and brought them to Sherwani's attention. She and a colleague, Michael Stehn, concluded that Akorn would need to withdraw the ANDA, and they elevated the issue to Silverberg.

- During Silverberg's discussion with Sherwani and Stehn, Silverberg was told that it was highly likely that there was false or fabricated data in the initial ANDA submitted to the FDA.

- During a meeting on August 17, 2017, Silverberg told Sherwani and Stehn that Akorn would not withdraw the ANDA and should instead pull samples and test them to see if the samples passed the test. Silverberg subsequently instructed Sherwani and Stehn to respond to the CRL, not to ask for an extension, and not to open an investigation in the data issues.

- Sherwani believed it was essential to conduct an investigation and to obtain an extension from the FDA. Sherwani asked Silverberg whether he was" allowing Regulatory Affairs to continue to submit inaccurate information" to the FDA. Silverberg argued that the FDA was asking about different data.

- Sherwani disagreed with Silverberg's positon and declined to sign the CRL.

- Silverberg instructed Sherwani that there should be "[n]o more emails."

- Silverberg signed the CRL on Sherwani's behalf while she was out of the office.

- By signing off on the CRL, Silverberg validated the attachments, which were not yet attached to the form he signed. The attachments included the false stability data. Sherwani had made clear to Silverberg that signing the CRL would constitute a resubmission of the false data.

211. For its part, thus far, NSF has allegedly identified at least two fraudulent submissions to the FDA, which involved different Akorn employees and at other Akorn sites, "as well as hundreds of serious and systemic violations across virtually every site."

212. In its site audits, NSF has found 34 "Major" findings which reflect "a systemic failure of a regulatory requirement, correlate[] to product defects, and/or represent[] uncorrected repeat findings cited by the FDA in previous inspections." According to NSF, these deficiencies, if known to the FDA, "would appear on a Form FDA 483 and may provide the basis for further enforcement action."

213. Similarly, NSF's audit of Akorn's ANDAs has purportedly identified two submissions of manipulated data to the FDA and hundreds of "major" deficiencies. For example, NSF's findings include:

- "Manipulat[ion]" of raw data. In one case, a failing result of 293 was changed to a passing result of 292 "to alter failing [results] into passing." NSF also identified a broader practice of "continuing to manipulate raw data" after results were obtained.
- "Back dating" notebook records.
- Deletion of raw data: "A raw data file was deleted . . . . No explanation provided."

214. Some of NSF's "Major" findings, include:

- The Vernon Hills audit concluded that "[i]n a large number of instances in *every notebook reviewed*, the date of the technician's work in the notebooks is a week or more later than the date that the HPLC sequences were run[.]"
- The Vernon Hills audit also determined that "[r]eview and verification of notebook activities is not always timely. In a large number of instances in every notebook reviewed, the verified date is months later, and in some cases more than a year after the work was performed." Further, "[t]he adequacy of notebook verification is questionable since the equations for some calculations are not described in the notebook."
- Another "Major" finding at Vernon Hills was that "[u]ser access levels are not appropriate to protect data from deletion or *further* manipulation."
- A "Major" finding at Cranbury was that laboratory notebooks were "lacking in traceability, legibility, [and] authenticity." Notebooks "lacking in . . . authenticity" is, of course, exactly what led to the multiple Burkert frauds. Nothing has changed.

- The Amityville audit found that analysts were able to "delete or modify" data on "[a]ll stand-alone instruments." Many of the instruments also did not have audit trails.

215. Despite these damning findings, NSF's investigation work is not yet complete, and it is still investigating additional instances of potential wrongdoing.

216. Moreover, Akorn has engaged in a troubling practice of using "trial injections." "Trial injections" refer to the injection and testing of a substance as a "trial" run, *i.e.*, for a purpose other than officially testing a drug product to generate data in support of a drug product application. The FDA has objected to the practice of conducting trial injections with actual samples of the drug product or drug substance to be tested in tests that are intended to support product applications submitted to the FDA or that will be used to justify the release of products manufactured for commercial distribution, because in those circumstances the trial injections may be used to achieve a specific result or to overcome an unacceptable result (a practice referred to as "testing into compliance"). By using trial injections "chemists could, for instance, 'game' the process by running multiple tests, and submit only the passing results while discarding the unofficial." Testing into compliance is inconsistent with the FDA's manufacturing standards.

217. NSF's Vernon Hills site audit discovered approximately 5,000 potentially problematic trial injections, of which approximately 50–75 require "deeper assessment." These potentially fraudulent tests involve "probably 20" analysts and at least "16 different products." NSF found that fabrication of data by a Vernon Hills employee was "not isolated but more systemic in nature."

218. In May 2018, Akorn finally engaged a specialist firm, PQE, to conduct a more comprehensive review of trial injections at all of its sites: "a full check of all potential trial injections for everything[.]" Even though this investigation is expected to take months, it is already clear that no results from this review can be trusted. The same analyst whom Akorn told the FDA,

on May 17, 2018, had been caught making a "deliberate change to force a passing result" was (as of May 22, 2018) assisting PQE by "going through and excluding [trial] injections" from its review.

> The FDA warned Akorn not to conduct trial injections in 2015. Akorn, however, ignored this directive.
>
> [According to] [t]alking points prepared by Akorn's counsel for a call with its Board of Directors on April 20, 2018, . . . ""the Company has identified ***many*** that are the type of ***problematic, unreported trial injections FDA has warned of.***" Its counsel also acknowledged that this "***problematic practice went on for four years and involved about 25 chemists.*** That means that there is a ***large volume*** of the 'trial injections' . . . that need to be reviewed."

(emphasis added).

219. Indeed, Akorn's advisors are concerned about receiving an AIP. During a conference call between Cravath and Ropes & Gray, the lead Roper & Gray partner expressed the concern that "[i]f audit reports make it look like there are similar issues across the company, FDA might see the need to get whole company under decree." He further recognized that the "[s]heer number of issues across all sites audited by NSF as we go could raise concern."

220. Allegedly, Akorn has identified other significant problems within its facilities. For example, twelve laboratory notebooks, belonging to "a variety of chemist[s]" are missing. This raises questions about whether Akorn can verify source data for the products for which those notebooks relate.

**E. Akorn Misleads the FDA Concerning its Regulatory Failures**

221. As detailed above, in the course of its investigations, NSF discovered the azithromycin fraud, whereby false testing data was provided to the FDA.

222. In order to comply with cGMP, the fraud was required to have been "fully investigated under the cGMP quality system" to determine the effects on patient safety, product quality, and data reliability, and the root causes.

223. Instead, Akorn hired Cravath, whose lead partner on the matter had never previously conducted an investigation into data integrity issues and had no familiarity with FDA regulations and guidance on data integrity.

224. For its part, Akorn relegated its GQC auditors to "answering only . . . very specific questions," and they were told "not to follow additional threads/items." As a result, although GQC had "a lot more info we can provide," it was told not to do so.

225. Then, three months after discovering the azithromycin fraud, Akorn finally disclosed it to the FDA. This disclosure was woefully deficient and allegedly included significant misrepresentations.

226. Akorn claimed that Silverberg had innocently provided false data to the FDA – even though Cravath had already learned that Silverberg knew the filing was false when he made it – as it was contradicted by witnesses and documents.

227. Akorn also misrepresented its data integrity program – the data integrity program that had many critical unresolved violations. Akorn represented to the FDA that it "has implemented extensive enhancements to procedures and controls to improve its data integrity program" including "IT infrastructure improvements." Akorn did not disclose that Akorn had blocked its IT department from implementing any data integrity fixes – not to mention Cerulean's very troubling findings.

228. Indeed, Akorn only implemented data integrity fixes after Fresenius terminated the Merger Agreement.

229. The problem with Akorn's presentation to the FDA was explained by Vice-Chancellor Laster in his post-trial Opinion:

> Akorn downplayed its problems and oversold its remedial efforts in a presentation to its primary regulator, the [FDA]. As one of Akorn's own experts recognized at

> trial, Akorn was not fully transparent with the FDA. put more bluntly, the presentation was misleading"

230. Indeed, Akorn's expert at trial conceded that Akorn was "not fully transparent" with the FDA during the meeting.

231. Vice-Chancellor Laster best summed-up Akorn's actual efforts to address its data integrity problems:

> Akorn only started making a concerted effort to address its data integrity issues in March 2018, after Fresenius had flagged Akorn's data integrity problems and prompted Akorn to uncover Silverberg's false CRL response, and after Akorn felt it had to try to get ahead of the problem by going to the FDA and committing to address its data integrity issues. At that point, Akorn formed an executive steering committee on data integrity remediation, which held its kickoff meeting on April 19, 2018. It took until June 7, 2018 for Akorn to assemble a list of the hundreds of deficiencies it had accumulated, many of which went back years. Over a year after receiving the Cerulean report, the Somerset facility had not taken any action to address the deficiencies it identified. Decatur had only completed "32% of the corrective actions thus far." By the time of trial, Akorn still did not have a remediation plan because it was still in the process of figuring out all of the deficiencies that the Company needed to address.

## V. Akorn Has Been Harmed

### A. Akorn's Actions Caused the Termination of the Merger Agreement

232. The merger price of $34 per share represented the true value of Akorn before giving effect to the value diminishing breaches of fiduciary duty engaged in by Akorn's Board and executives. As explained by the Delaware Supreme Court in *DFC Global Corp. v. Muirfield Value Partners, L.P.*, "the sale value resulting from a robust market check will often be the most reliable evidence of fair value . . . ." 172 A.3d 346, 366 (2017).

233. After the close of trading on February 26, 2018, Fresenius announced that it had opened an investigation "into alleged breaches of FDA data integrity requirements relating to

product development at Akorn, Inc."[36] This news caused Akorn's stock price to drop from its close at $30.28 per share on February 26, 2018, to $18.65 by the close of trading on February 27, 2018.

234. On April 22, 2018, Fresenius made the following public announcement terminating the Merger Agreement:

> **Fresenius terminates merger agreement with Akorn**
>
> Fresenius has decided today to terminate the company's merger agreement with Akorn, due to Akorn's failure to fulfill several closing conditions.
>
> Fresenius' decision is based on, among other factors, material breaches of FDA data integrity requirements relating to Akorn's operations found during Fresenius' independent investigation. Fresenius offered to delay its decision in order to allow Akorn additional opportunity to complete its own investigation and present any information it wished Fresenius to consider, but Akorn has declined that offer.[37]

235. This news caused a further drop in Akorn's stock price, from its close at $19.70 per share on April 20, 2018, to close at $13.05 per share on April 23, 2018, the next day of trading.

236. On April 27, 2018, Akorn initiated suit against Fresenius in the Chancery Court of Delaware seeking specific performance from Fresenius requiring Fresenius to close on the merger.

237. On May 1, 2018, Fresenius filed its Answer and Counterclaims seeking declaration that Akorn breached the Merger Agreement as well as damages, costs, and attorneys' fees in connection with Akorn's breach.

238. Beginning on July 9 and continuing through July 13, 2018, Vice Chancellor Laster of the Chancery Court of Delaware conducted a bench trial, which was followed by significant post-trial briefing.

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[36] Fresenius, Investigation into Alleged Breaches of FDA Data Integrity Requirements at Akron, Inc.; Fresenius Aims at Strong Growth in 2018 and Confirms Mid-Term Growth Targets (Feb. 26, 2018).

[37] Fresenius, Fresenius Terminates Merger Agreement with Akorn (Apr. 22, 2018).

239. On October 1, 2018, Vice Chancellor Laster held that Akorn breached the Merger Agreement and that Fresenius was justified in terminating the Merger Agreement, killing the $4.8 billion deal. "Any second thoughts that Fresenius had about the Merger Agreement were justified by unexpected events at Akorn," Vice Chancellor Laster wrote, citing data integrity issues that Fresenius discovered after the deal's announcement.[38]

240. The breaches of fiduciary duty by Akorn's Board and executives caused termination of the Merger Agreement. This has harmed Akorn by reducing the fair value of Akorn from $34 per share to $5.65 per share, representing damages to Akorn in the amount of $2.64 billion.

**B. Akorn Is at Serious Risk of Regulatory Action by the FDA**

241. One of the penalties that the FDA could impose on Akorn is invoking its Application Integrity Policy ("AIP"), which would suspend all of Akorn's drug applications until Akorn can demonstrate that its data is reliable. Even if the FDA does not impose an AIP, it could impose a lesser penalty that causes a significant harm to Akorn.

242. As early as January 19, 2018, after discussions about the azithromycin fraud, Akorn's Head of Regulatory Affairs remarked that "[t]hey're going to invoke application integrity policy[.]" In another call shortly thereafter, Akorn and its advisors discussed the AIP and whether the FDA would "suspend approvals of other applications."

243. Nevertheless, under pressure from Fresenius, on March 16, 2018, Akorn notified the FDA of the azithromycin fraud, including Silverberg's submission of false data in August 2017 as in response to the Total Response Letter.

[38] Eric Sagonowsky, "Judge Frees Fresenius from Buyout, Citing 'Extensive and Recurring" Data Problems," *Fierce Pharma* (Oct. 1, 2018), *available at* https://www.fiercepharma.com/pharma/citing-extensive-and-recurring-data-problems-at-akorn-judge-rules-fresenius-legally-ended.

244. Reflecting Akorn's fear of an AIP, when it notified the FDA of the azithromycin fraud, Akorn claimed that Silverberg's submission of false information to the FDA was unintentional – even though Akorn knew that Silverberg's submission was intentional. Akorn's presentation to the FDA also allegedly made false claims about Akorn's data integrity compliance.

245. Following this disclosure, on April 5, 2018, Cravath's lead partner informed another Cravath partner of NSF's findings of trial injections at Akorn's Vernon Hills site, writing:

> ***[G]iven how prevalent this bad practice was, the FDA is likely to have a very negative reaction to our report …*** Potential FDA reactions include (1) suspension of review of all pending submissions; (2) mandating review by a third party of product released for the market; and—the worst— (3) 'AIP' (Application Integrity Policy), which requires a third-party monitor to oversee all activity at Akorn's sites.

246. On May 16, 2018, during its investigation of Decatur, the FDA issued a twenty-four page Form 483 which identified thirteen categories of deficiencies. The Form 483 included many issues including:

- Failure to maintain complete data derived from all testing and to ensure compliance with established specifications and standards pertaining to data retention and management[.]
- Failure to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed.
- Repeat observations from 11/2004 9/2006, 8/2007, 6/2009 & 2017.
- Repeat observation from 11/2004.

247. On August 9, 2018, the FDA formally placed the Decatur facility on OAI status, noting the possibility of regulatory or enforcement action. The two prior times when Akorn facilities were on OAI status, it took six months to a year to clear the facility.

248. The FDA has since declined to approve two ANDAs, citing quality issues at Decatur. Akorn has also received two CRLs for products that would be manufactured at Decartur.

249. On August 30, 2018, the FDA issued a Form 483 that allegedly found numerous violations at Akorn's Somerset facility which were first identified in 2015 or earlier. The Form 483 concluded that "there is limited assurance in the reliability of data submitted to the Agency and generated for commercial batches." The Form 483 allegedly detailed "dozens of serious regulatory violations, including many of the types of DI violations that were the subject of evidence and expert testimony at trial." According to Fresenius's description of the Form 483, the document revealed that:

- Akorn was distributing batches of adulterated sterile eye drops that failed four separate stability tests;
- Akorn was forced to recall these batches during the inspection itself;
- Akorn could not provide data for those batches at the beginning of the FDA's inspection, and the inspectors later witnessed Akorn employees retrospectively modifying the relevant laboratory notebook records during the inspection;
- Akorn conducted trial injections as a "widespread practice," this practice dated back to at least 2015, and no "corrective measures to prevent this practice were implemented until" May 2018;
- Akorn's investigation of its trial injections was "inadequate";
- as a result, "there is limited assurance in the reliability of data submitted to the Agency and generated for commercial batches"; and
- Akorn failed to exercise "[a]ppropriate controls . . . over computers or related systems" to prevent unauthorized access or manipulation of its data.

250. The Form 483 identified other serious violations. For example:

- Akorn "invalidated" negative test results in more than 70% of cases between January 2017 and July 2018 "without adequately supporting [the reasons for [invalidation] with scientific evidence" (Ex. A, -519-20); The investigations into these failing results did not "determine why the[y] . . . kept on reoccurring nor were there effective CAPAs implemented to minimize these incidents going forward";
- Akorn also failed to review laboratory notebook testing data for months, and an Akorn employee admitted to the FDA that "due to personnel

> resources issue[s], they could not review the notebooks in a timely manner"; and
>
> - Akorn's procedures for avoiding contamination in its sterile products were inadequate — for instance, in one case, an Akorn employee "touch[ed] and wipe[d] the bottom of shoe covered foot and then proceeded to touch the filling line machine equipment surfaces without any sanitization in between."

251. While it is too early to know what Akorn's response to the Form 483 will be and what penalties the FDA may impose, the FDA's investigatory findings in the Form 483 further heighten the risk to Akorn that the FDA will invoke AIP or other serious regulatory sanctions.

252. In addition to these serious findings, "Akorn provided the FDA with a misleading description of its investigation, its views on whether Silverberg acted knowingly, and the state of Akorn's data integrity efforts. Akorn also concealed a troubling incident in which Silverberg sought to coordinate stories with Sherwani about the azithromycin incident and destroy evidence of the coordination."

253. Akorn's FDA problems only became worse as the trial went on. According to the Opinion:

> Perhaps most strikingly, by letter dated September 3, 2018, Akorn reported to the court that on August 22, during the later stages of the FDA's investigation, someone had erased the database at Somerset for a high accuracy liquid particle counter along with the local backup file and the associated electronic security logs. FDA inspectors had been on site at Somerset intermittently between July 23 and August 30. Akorn has reported the incident to law enforcement. Given the timing of the deletion, it is reasonable to infer that the perpetrator may have been trying to hide information from the FDA, or from personnel who would follow up on the deficiencies that the FDA identified in its Form 483.

254. In his post-trial opinion, Vice-Chancellor Laster described Akorn as "a company in persistent, serious violation of FDA requirements with a disastrous culture of noncompliance." He explained that:

> The systemic failures at Akorn raise questions about the accuracy and reliability of all of its data, regardless of site or product. As a result, Akorn cannot meet its

> burden to prove to the FDA that its data is accurate. To the contrary, Akorn's products and facilities are known not to comply with cGMP and FDA requirements, as shown by the reports of its own internal audit team. Akorn does not make products where quality issues can be overlooked until problems arise. As Henriksson testified, "[W]e are talking about drugs which are used by people … who are critically ill … [and] many of those products … are going to be injected into people."

255. Vice-Chancellor Laster opined that Akorn would need to undergo a complete investigation and then remediation of data integrity issues, finding that the "financial impact of Akorn's data integrity issues" is "approximately $900 million."

**C. Akorn Is Exposed to Billions of Dollars in Damages to Fresenius**

256. Akorn is also subject to significant additional damages due to its conduct in breaching the representations and warranties in the Merger Agreement. Pursuant to Section 7.02 of the Merger Agreement, even if the merger is terminated, "no such termination shall relieve any party from liability for damages to another party resulting from a knowing and intentional breach of this Agreement or from fraud."

257. Thus, the termination of the Merger Agreement ordered by Vice Chancellor Laster does not eliminate Akorn's liability for a knowing and intentional violation of the terms and conditions of the Merger Agreement.

258. Fresenius's CEO, Stephan Sturm, testified that Akorn's mistakes caused $1.9 billion in damage to its business. Now that it won its declaratory relief action in Delaware Chancery Court, Fresenius is likely to sue Akorn for the $1.9 billion in damages it claims were caused to its business by Akorn's conduct. Akorn is thus exposed to billions more in damages due to the Individual Defendants' wrongdoing.

## VI. Akorn's Senior Management and Board Are Responsible for the Harm to the Company

### A. Quality Oversight Committee

259. The members of the Quality Oversight Committee who received audit reports and were aware of serious data integrity and compliance problems by December 2016, included: Defendant Rai; Defendant Silverberg; Akorn's COO; Board Defendants Weinstein, Johnson and Tambi; and other top Akorn executives.

260. Also, Defendants Rai, Weinstein, Johnson, and Tambi approved the Merger Agreement on or about April 24, 2017, despite having actual knowledge by virtue of their receiving audit reports as members of the Quality Oversight Committee that the representations therein were false, making no efforts to come into compliance, and causing additional subsequent breaches. This was a breach of their fiduciary duties.

261. The members of the Quality Oversight Committee who received Cerulean's May 2017 audit report and were therefore aware of potential criminal liability resulting from data integrity and compliance violations, included: Defendant Rai; Defendant Silverberg; Akorn's COO; Board Defendants Weinstein, Johnson and Tambi; and other top Akorn executives. Nevertheless, "no actions were taken in response" to Cerulean's May 2017 Somerset audit report until March 2018. This represented a breach of fiduciary duty by the members of the Quality Oversight Committee.

262. The members of the Quality Oversight Committee, which included Defendants Rai, Silverberg, Weinstein, Johnson, and Tambi allowed the Company to cancel external audits, limit internal audits, and freeze data integrity projects despite knowing of Cerulean's May 2017 audit report identifying possible criminal liability and that many other past findings of serious problems had never been addressed. This constituted a breach of their fiduciary duties.

263. The members of the Quality Oversight Committee's (which included Defendants Rai, Silverberg, Weinstein, Johnson, and Tambi) further breached their fiduciary duties when they discovered throughout late 2017, that Akorn had failed to perform remediation efforts with regard to past "critical" audit findings and nevertheless failed to correct these problems.

264. The members of the Quality Oversight Committee's (which included Defendants Rai, Silverberg, Weinstein, Johnson, and Tambi) decision to suspend the Quality Oversight Committee or to allow it to be suspended, in light of the serious data integrity and other issues facing the Company, constituted breaches of fiduciary duty.

265. The members of the Quality Oversight Committee's (which included Defendants Rai, Silverberg, Weinstein, Johnson, and Tambi) further breached their fiduciary duties by failing to immediately notify the FDA when it learned of false submissions to the FDA and then when it did notify the FDA three months later, provided incomplete and incorrect information.

**B. Audit Committee**

266. The members of the Audit Committee who received audit reports and were aware of serious data integrity and compliance problems by December 2016, were: Defendants Abramowitz, Johnson, Meyer (Chair), and Rappuhn.

267. Defendants Abramowitz, Johnson, Meyer, and Rappuhn agreed to execute the Merger Agreement on April 24, 2017, despite having actual knowledge by virtue of their receiving audit reports as members of the Audit Committee that the representations therein were false, making no efforts to come into compliance, and causing additional subsequent breaches. This was a breach of their fiduciary duties.

268. The members of the Audit Committee who received Cerulean's May 2017 audit report and were therefore aware of potential criminal liability resulting from data integrity and compliance violations, were: Defendants Abramowitz, Johnson, Meyer (Chair), and Rappuhn.

Nevertheless, "no actions were taken in response" to Cerulean's May 2017 Somerset audit report until March 2018. This was a breach of their fiduciary duties.

269. The members of the Audit Committee, including Defendants Abramowitz, Johnson, Meyer (Chair), and Rappuhn further breached their fiduciary duties when they discovered throughout late 2017, that Akorn had failed to perform remediation efforts with regard to past "critical" audit findings and nevertheless failed to correct these problems.

270. The members of the Audit Committee, including Defendants Abramowitz, Johnson, Meyer (Chair), and Rappuhn, allowed the Company to cancel external audits, limit internal audits, and freeze data integrity projects despite knowing of Cerulean's May 2017 audit report identifying possible criminal liability and that many other past findings of serious problems had never been addressed. This constituted a breach of their fiduciary duties.

271. The members of the Audit Committee, including Defendants Abramowitz, Johnson, Meyer (Chair), and Rappuhn, decision to suspend the Quality Oversight Committee or to allow it to be suspended, in light of the serious data integrity and other issues facing the Company, constituted breaches of fiduciary duty.

272. The members of the Audit Committee, including Defendants Abramowitz, Johnson, Meyer (Chair), and Rappuhn, further breached their fiduciary duties by failing to immediately notify the FDA when it learned of false submissions to the FDA and then when it did notify the FDA three months later, provided incomplete and incorrect information.

**C. The Board of Directors**

273. The members of the Board of Directors who had knowledge of illegal and serious data integrity failures by December 2016, included: Weinstein, Abramowitz, Graves, Johnson, Meyer, Rappuhn, and Tambi, as well as former Director Kapoor.

274. Defendants Graves and Kapoor, as Board members, were notified by the members of the Audit Committee of the "critical" data integrity violations amounting to violations of law, and thereafter knowingly agreed to execute the Merger Agreement on or about April 24, 2017, despite having actual knowledge that the representations therein were false, making no efforts to come into compliance, and causing additional subsequent breaches. This was a breach of their fiduciary duties.

275. Defendants Graves and Kapoor, as Board members, were notified by the members of the Audit Committee of Cerulean's May 2017 audit report and was therefore aware of potential criminal liability resulting from data integrity and compliance violations. Nevertheless, "no actions were taken in response" to Cerulean's May 2017 Somerset audit report until March 2018. This was a breach of their fiduciary duties.

276. Defendants Graves and Kapoor, allowed the Company to cancel external audits, limit internal audits, and freeze data integrity projects despite knowing of Cerulean's May 2017 audit report identifying possible criminal liability and that many other past findings of serious problems had never been addressed. This constituted a breach of their fiduciary duties.

277. Defendants Graves and Kapoor further breached their fiduciary duties when they discovered throughout late 2017, that Akorn had failed to perform remediation efforts with regard to past "critical" audit findings and nevertheless failed to correct these problems.

278. Defendants Graves's and Kapoor's decisions to suspend the Quality Oversight Committee or to allow it to be suspended, in light of the serious data integrity and other issues facing the Company, constituted breaches of fiduciary duty.

279. Defendants Graves and Kapoor further breached their fiduciary duties by failing to immediately notify the FDA when they learned of false submissions to the FDA and then when Akorn did notify the FDA three months later, provided incomplete and incorrect information.

**D. Interests of the Directors and Senior Management**

280. In 2016 and 2017, the Director Defendants were compensated by the Company as follows:[39]

| **Director** | **2016 Retainer Fee** | **2016 Stock Options** | **2016 Restricted Stock Options** | **2017 Retainer Fee** | **2017 Stock Options** | **2017 Restricted Stock Options** | **Total** |
|---|---|---|---|---|---|---|---|
| John N. Kapoor | $125,000 | $137,500 | $137,500 | | | | **$400,000** |
| Alan Weinstein | $120,000 | $137,500 | $137,500 | $124,583 | — | $267,713 | **$787,296** |
| Kenneth Abramowitz | $88,750 | $137,500 | $137,500 | $90,000 | — | $267,713 | **$721,463** |
| Adrienne Graves | $115,000 | $137,500 | $137,500 | $111,250 | — | $267,713 | **$768,963** |
| Ronald Johnson | $113,750 | $137,500 | $137,500 | $115,000 | — | $267,713 | **$771,463** |
| Steven Meyer | $107,500 | $137,500 | $137,500 | $100,000 | — | $267,713 | **$750,213** |
| Terry Rappuhn | $120,000 | $137,500 | $137,500 | $123,125 | — | $267,713 | **$157,168** |
| Brian Tambi | $78,750 | $137,500 | $137,500 | $82,500 | — | $267,713 | **$703,963** |

281. Defendant Rai's compensation in 2016 and 2017 was as follows:

| **RAJ RAI** | | | | | | |
|---|---|---|---|---|---|---|
| **Year** | **Base Salary** | **Incentive Award** | **Stock Options** | **Restricted Stock Options** | **Other Compensation** | **Total** |
| 2016 | $824,000 | $1,235,308 | $4,290,525 | $800,010 | $4,923 | $7,154,766 |
| 2017 | $857,000 | — | — | $3,337,274 | $945 | $4,195,219 |
| **TOTALS** | | | | | | **$11,349,985** |

[39] This table does not reflect Defendant Kapoor's compensation for 2017.

282. In addition to the foregoing, each Defendant was expected to receive a significant windfall upon closing of the Merger.

283. The following table shows the impact of the Merger of stock options held by the Director Defendants and certain officers of the Company:

| **Directors** | Unvested Company Stock Options (#) | ($) | Company RSUs Granted Prior to Date of Merger Agreement (#) | ($) | Company RSUs Granted Following Date of Merger Agreement (#) | ($) | **Total** ($) |
|---|---|---|---|---|---|---|---|
| John N. Kapoor, Ph.D. | 5,800 | $26,100 | 2,330 | $79,220 | 8,088 | $274,992 | $380,312 |
| Kenneth S. Abramowitz | 5,800 | $26,100 | 2,330 | $79,220 | 8,088 | $274,992 | $380,312 |
| Adrienne L. Graves, Ph.D. | 5,800 | $26,100 | 2,330 | $79,220 | 8,088 | $274,992 | $380,312 |
| Ronald M. Johnson | 5,800 | $26,100 | 2,330 | $79,220 | 8,088 | $274,992 | $380,312 |
| Steven J. Meyer | 5,800 | $26,100 | 2,330 | $79,220 | 8,088 | $274,992 | $380,312 |
| Terry Allison Rappuhn | 5,800 | $26,100 | 2,330 | $79,220 | 8,088 | $274,992 | $380,312 |
| Brian Tambi | 5,800 | $26,100 | 4,338 | $147,492 | 8,088 | $274,992 | $448,584 |
| Alan Weinstein | 5,800 | $26,100 | 2,330 | $79,220 | 8,088 | $274,992 | $380,312 |
| **Executive Officers** | | | | | | | |
| Raj Rai | 340,334 | $2,679,101 | 51,554 | $1,752,836 | 100,824 | $3,428,016 | $7,859,953 |
| Joseph Bonaccorsi | 107,440 | $840,166 | 32,856 | $1,117,104 | 33,529 | $1,139,986 | $3,097,256 |
| Steven Lichter | 176,488 | $630,846 | 1,906 | $64,804 | 9,853 | $335,002 | $1,030,652 |

284. Based on this information, it is clear that more than 50% of each Defendant's compensation was contingent. With such a high proportion of contingent compensation, each Director Defendant was incentivized to obtain FDA approval of as many products as possible and to avoid having any products be suspended by the FDA, while spending as little money as possible

on compliance efforts. Thus, the breaches of fiduciary duty identified above implicate their duty of loyalty.

285. The following table details potential payments to certain officers of the Company upon closing of the Merger:

| Name | Cash ($) | Equity ($) | Benefits ($) | Total ($) |
|---|---|---|---|---|
| Raj Rai | $6,427,500 | $7,859,953 | $39,699 | $14,327,152 |
| Joseph Bonaccorsi | $1,596,000 | $3,097,256 | $26,466 | $4,719,722 |
| Steven Lichter | $670,000 | $1,030,652 | $13,233 | $1,713,885 |

286. In addition to the foregoing, the Merger would have resulted to a windfall to Akorn's directors' and officers' shareholdings in Akorn as follows:

| Beneficial Owner | Shares Beneficially Owned | Value of Shares Prior to Merger Rumors (at $25.45 per share) | Value of Shares at Merger Price | Windfall |
|---|---|---|---|---|
| Directors: | | | | |
| John N. Kapoor, Ph.D. | 28,465,612 | $ 724,449,825 | $ 967,830,808 | $ 243,380,983 |
| Kenneth S. Abramowitz | 46,570 | $ 1,185,207 | $ 1,583,380 | $ 398,174 |
| Adrienne L. Graves, Ph.D. | 38,886 | $ 989,649 | $ 1,322,124 | $ 332,475 |
| Ronald M. Johnson | 148,151 | $ 3,770,443 | $ 5,037,134 | $ 1,266,691 |
| Steven J. Meyer | 117,442 | $ 2,988,899 | $ 3,993,028 | $ 1,004,129 |
| Terry Allison Rappuhn | 28,633 | $ 728,710 | $ 973,522 | $ 244,812 |
| Brian Tambi | 73,461 | $ 1,869,582 | $ 2,497,674 | $ 628,092 |
| Alan Weinstein | 97,943 | $ 2,492,649 | $ 3,330,062 | $ 837,413 |
| Executive Officers: | | $ - | $ - | $ - |
| Raj Rai | 2,403,395 | $ 61,166,403 | $ 81,715,430 | $ 20,549,027 |
| Joseph Bonaccorsi | 456,609 | $ 11,620,699 | $ 15,524,706 | $ 3,904,007 |
| Steven Lichter | 126,132 | $ 3,210,059 | $ 4,288,488 | $ 1,078,429 |
| Directors and Executive Officers as a group (15 persons) | 32,557,918 | $ 828,599,013 | $ 1,106,969,212 | $ 278,370,199 |

287. In addition, each defendant was incentivized to avoid disclosing, discovering, or remediating any data integrity violations or other regulatory issues until the Merger with Fresenius closed, as closing of the Merger would have provided each of them with very significant additional compensation, further breaching their duty of loyalty.

288. Accordingly, each of the Defendants benefitted from Akorn's failure to remedy known compliance issues.

## DERIVATIVE ALLEGATIONS

289. Pursuant to LA Rev. Stat. § 12.1-742.1:

> §1-742.1. Petition in derivative proceeding.
>
> The petition in a derivative proceeding shall do all of the following:
>
> (1) Allege that the plaintiff meets the standing requirements of R.S. 12:1-741.
>
> (2) Allege either that the plaintiff made demand upon the corporation at least ninety days before the filing of the petition as required by R.S. 12:1-742 or that the plaintiff made the demand and, for reasons alleged in the petition, the filing of the petition before the expiration of the ninety-day period complies with R.S. 12:1-742.
>
> (3) Join as defendants the corporation and the obligor on the obligation sought to be enforced.
>
> (4) Include a prayer for judgment in favor of the corporation and against the obligor on the obligation sought to be enforced.
>
> (5) Be verified by the affidavit of the plaintiff or his counsel.
>
> Acts 2014, No. 328, §1, eff. Jan. 1, 2015.

290. As alleged above in paragraph 13, Plaintiff meets the standing requirements of R.S. 12:1-741, as Plaintiff was a shareholder of the Company at the time of the acts complained of herein or became a shareholder through transfer by operation of law from one who was a shareholder at that time. Further, Plaintiff can fairly and adequately represent the interests of the Company in enforcing the right of the Company.

291. Plaintiff made demand upon the Company as provided in LA Rev. Stat. § 12.1-742.

292. Pursuant to LA Rev. Stat. § 12.1-742:

> §1-742. Demand
>
> No shareholder may commence a derivative proceeding until the following conditions are satisfied:
>
> (1) A written demand has been made upon the corporation to take suitable action.
>
> (2) Ninety days have expired from the date the demand was made unless the shareholder has earlier been notified that the demand has been rejected by the corporation or unless irreparable injury to the corporation would result by waiting for the expiration of the ninety-day period.

Acts 2014, No. 328, §1, eff. Jan. 1, 2015.

293. On June 29, 2018, Plaintiff made a demand upon Akorn's Board of Directors, which was delivered to Akorn's corporate headquarters on July 2, 2018 at 9:54 am (the "Demand"). A copy of the Demand is attached hereto as Exhibit A.

294. In the Demand, Shareholder demanded that the Board take action, including:

> Corporate Governance Reforms and Litigation
>
> - Identify, terminate or remove for cause, and initiate litigation against any individual or entity that engaged in, had supervisory authority over, or possessed oversight duties concerning the alleged misconduct ("Implicated Individuals").
> - Require the Implicated Individuals to return to Akorn all salaries, bonuses, and the value of other remuneration, of whatever kind, paid to them by the Company during the time they were in breach of the fiduciary duties they owed to Akorn.
> - Commence a civil action against the Implicated Individuals to recover for the benefit of the Company the amount of damages sustained by the Company as a result of their breaches of fiduciary duties, including claims for contribution or indemnification to the extent that the Company has or will incur as liabilities from securities, consumer and/or regulatory actions.
> - Provide all Board members with a copy of this demand letter as notice of a potential derivative lawsuit

Internal and External Controls

- Conduct an external data integrity assessment of all the Company's sites and immediately implement all findings, including all steps identified by Cerulean during its assessment of the Company's Decatur, Illinois site, as necessary to remediate all data integrity control issues.

- Appoint an independent outside monitor with broad oversight authority to implement and administer a system of internal controls and accounting systems sufficient to satisfy FDA requirements including, but not limited to, engaging an outside Compliance Consultant to review and guide Company in improving its data integrity policy, procedures, and practices.

- Direct additional resources to IT staffing and training.

- Implement a system to electronically track and monitor lab notebooks with built-in redundancies.

295. Ninety-days from July 12, 2018 was October 10, 2018. Accordingly, more than ninety days have expired from the date the Demand was received by Akorn.

296. Akorn has neither acknowledged nor responded to Plaintiff's Demand, and thus has constructively denied the Demand.

297. Despite having denied the Demand, as described above, each Board member breached his or her fiduciary duties to the Company. As a result, none of the Director Defendants is capable of evaluating the Demand in good faith.

298. Each of Akorn's Directors personally breached their fiduciary duties, as stated herein, such that they are liable to the Company for the losses sustained by the Company as a result of its illegal conduct, as well as securities, consumer and/or regulatory actions.

## CAUSES OF ACTION

### FIRST CLAIM FOR RELIEF

**Breach of Fiduciary Duty**
**(Against All Defendants)**

299. Plaintiff incorporates by reference and realleges each of the foregoing allegations as though fully set forth in this paragraph.

300. Each of the Defendants owed and owes fiduciary duties to Akorn and its stockholders. By reason of their fiduciary relationships, Defendants specifically owed and owe Akorn the highest obligation of good faith, fair dealing, loyalty, and due care in the administration and management of the affairs of the Company, including the Company's internal controls and regulatory compliance functions.

301. Each of the Defendants consciously and deliberately breached their fiduciary duties of candor, good faith, loyalty, and reasonable inquiry to Akorn and its stockholders in at least the following ways:

- Being aware of, yet failing to address critical, systemic, and repeated data integrity and other regulatory violations prior to April 2017;
- Executing the Merger Agreement despite having actual knowledge that the representations therein were false;
- Being aware of, yet failing to address and taking no actions in response to critical, systemic, repeated, and possibly criminal data integrity and compliance violations;
- Cancelling external audits, limiting internal audits, freezing data integrity projects despite being aware of critical, systemic, repeated, and possibly criminal data integrity and compliance violations.
- Suspending the activities of the Quality Oversight Committee despite being aware of critical, systemic, repeated, and possibly criminal data integrity and compliance violations; and
- Failing to immediately notify the FDA after learning about false submissions to the FDA, and then downplaying Akorn's problems, overselling Akorn's remedial

> efforts, and not being transparent with the FDA in a presentation when it finally disclosed some of its problems.

302. Defendants, individually and in concert, engaged in the above referenced conduct in intentional, reckless, or grossly negligent breaches of the fiduciary duties they owed to Akorn to protect its rights and interests.

303. Defendants had actual knowledge of the misstatements and omissions of material facts set forth in this Complaint, or acted with reckless disregard for the truth, in that they failed to ascertain and to disclose such facts, even though such facts were available to them.

304. These actions were not a good-faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

305. Additionally, Defendants have specific fiduciary duties as defined by the Company's corporate governance documents, including the Code of Conduct Ethics and the charters of various Board committees that, had they been discharged in accordance with Defendants' obligations, would have necessarily prevented the misconduct and the consequent harm to the Company alleged in this Complaint.

306. Defendants conspired to abuse, and did abuse, the control vested in them by virtue of their positions in the Company.

307. Akorn's certificate of incorporation contains a provision eliminating the monetary liability of directors for certain breaches of duty. However, this provision does not apply:

> (i) for any breach of the director's or officer's duty of loyalty to the Corporation or its shareholders; (ii) for acts or omissions not in good faith or which involve intentional misconduct or knowing violation of law; (iii) for liability under Section 92D of the Louisiana Business Corporation Law; or (iv) for any transaction from which the director or officer derives an improper personal benefit.

Restated Articles of Incorporation, Art. XII (Sept. 16, 2004).

308. However, the Louisiana Business Corporation Law, § 12:1-832 provides as follows:

> A. Except to the extent that the articles of incorporation limit or reject the protection against liability provided by this Section, no director or officer shall be liable to the corporation or its shareholders for money damages for any action taken, or any failure to take action, as a director or officer, except for one of the following:
>
> (1) A breach of the director's or officer's duty of loyalty to the corporation or the shareholders.
>
> (2) An intentional infliction of harm on the corporation or the shareholders.
>
> (3) A violation of R.S. 12:1-833.
>
> (4) An intentional violation of criminal law.
>
> B. The liability of a director or officer for conduct described in Paragraphs (A)(1) through (4) of this Section may not be limited or eliminated, but the corporation may purchase insurance against that liability as provided in R.S. 12:1-857.
>
> C. For purposes of this Section, the duty of loyalty does not include any duty to act with any degree of care in the exercise of the director's or officer's responsibilities to the corporation or its shareholders.
>
> D. A provision in a corporation's articles of incorporation that became effective before January 1, 2015, and that purports to protect a director or officer of the corporation against monetary liability to the corporation or its shareholders, shall not operate as a limitation of the protection against liability provided by this Section except to the extent that it provides less protection against liability than was permitted by the law in effect at the time the provision became effective.

La. Stat. Ann. § 12:1-832

309. Accordingly, to the extent Akorn's exculpatory provision applies to the Director Defendants' acts or omissions while acting in their capacity as directors, it cannot immunize them from (i) any non-monetary liability, (ii) monetary liability for their breaches of the duty of loyalty, (iii) monetary liability for acts or omissions not in good faith or that involved intentional

misconduct or a knowing violation of law, or (iv) monetary liability in connection with any transaction from which they derived an improper personal benefit.

310. As detailed in this Complaint, the Director Defendants' misconduct: (i) involved breaches of their duty of loyalty; (ii) involved acts or omissions not in good faith or that involved intentional misconduct or a knowing violation of law; and (iii) at least for Kapoor, occurred in connection with a transaction from which he derived improper personal benefits. Akorn's exculpatory provision therefore cannot immunize the Director Defendants from liability for that misconduct.

311. Additionally, Silverberg, Rai, and Kapoor are not entitled to claim any immunity under the Articles of Incorporation to the extent this claim is asserted against them in their capacities as officers and/or controlling shareholders of the Company.

312. Defendants' actions as detailed in this Complaint were not a good-faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

313. As a direct and proximate result of Defendants' breaches of their fiduciary obligations, Akorn has sustained and continues to sustain significant damages. As a result of the misconduct alleged in this Complaint, Defendants are liable to the Company.

**SECOND CLAIM FOR RELIEF**

**Unjust Enrichment**
**(Against All Defendants)**

314. Plaintiff incorporates by reference and realleges each of the foregoing allegations as though fully set forth in this paragraph.

315. During the Relevant Period, Defendants received bonuses, stock options, stock, or similar compensation from Akorn that was tied to the Company's financial performance, or otherwise received compensation that was unjust in light of Defendants' bad faith conduct,

violation of the Company's code of ethics, and self-dealing. Indeed, in 2016 and 2017 alone, this compensation exceeded $16 million.

316. Plaintiff, as shareholder and representative of Akorn, seeks restitution from Defendants and seeks an order of this Court disgorging all profits, benefits, and other compensation — including any salary, options, performance-based compensation, and stock — obtained by Defendants due to their wrongful conduct alleged in this Complaint.

**THIRD CLAIM FOR RELIEF**

**Violation of Section 14(a) of the Exchange Act and SEC Rule 14a-9**
**(Against the Director Defendants and Defendant Rai)**

317. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth in this paragraph, except to the extent those allegations plead knowing or reckless conduct by the Director Defendants and Defendant Rai. This claim is based solely on negligence, not on any allegation of reckless or knowing conduct by or on behalf of the Director Defendants.

318. SEC Rule 14a-9, 17 C.F.R. § 240.14a-9(a), promulgated under Section 14(a) of the Exchange Act, provides:

> No solicitation subject to this regulation shall be made by means of any proxy statement form of proxy, notice of meeting or other communication, written or oral, containing any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading or necessary to correct any statement in any earlier communication with respect to the solicitation of a proxy for the same meeting or subject matter which has become false or misleading.

319. The Director Defendants and Defendant Rai negligently issued, caused to be issued, and participated in the issuance of materially misleading written statements to stockholders that were contained in the 2016 Special Proxy Statement and the 2017 Annual Proxy Statement (collectively, the "Proxy Statements").

320. The Proxy Statements misstated or failed to disclose pervasive unlawful business practices at Akorn predicated on systematic violation of FDA rules and regulations, including forged entries in Akorn's journals and deliberate changes in testing procedures to force a passing result, that existed when the Proxy Statements were filed, which unlawful conduct put Akorn significantly at risk and contradicted Akorn's representations that it was in compliance with applicable FDA rules and regulations.

321. The Proxy Statements were also materially false and misleading because they failed to disclose that:

(a) Akorn's senior management and board had been warned about regulatory violations that were so severe that Akorn's senior management should be concerned about potential criminal liability;
(b) Akorn was cancelling external audits, limited internal audits, and freezing data integrity projects despite being aware of critical, systemic, repeated, and possibly criminal data integrity and compliance violations;
(c) Members of Akorn's Board were "concerned" about the "repetitiveness of issues between sites and across sites identified during audits & external inspections" and that Akorn needed to implement "corrective actions on a global basis."
(d) the many other violations of FDA rules and regulations as detailed herein.

322. The detailed facts regarding Akorn's repeated and pervasive violations of FDA regulations are set forth in this complaint, and incorporated into this count by reference. For example, in the Delaware litigation between Akorn and Fresenius, where substantial evidence was submitted, including live testimony, Akorn "concede[d] that there are forged notebook entries involving five other products, including three products for which such data was submitted to the FDA." Akorn's admission of these facts was borne out by the following evidence from the Delaware litigation:

> Azithromycin: In December 2012, Akorn submitted fraudulent test results to the FDA in an ANDA for an antibiotic named azithromycin. Somerset lab supervisor Jim Burkert, when pressured to quickly provide test results for particulate matter (a measure of undissolved solids in the product), forged the

> purported results in the lab notebook of another chemist. . . The Somerset facility did not have the technology to conduct the test. Shortly thereafter, the fabricated data was submitted to the FDA in an ANDA on December 21, 2012. Although an Executive Director of Quality at Akorn's Somerset facility identified forged entries in notebooks as early as November 2014, there is no evidence that the forged entries were investigated.
>
> By mid-2016, senior Akorn quality executives, including Mark Silverberg, became aware of the forged entries. Silverberg instructed the Somerset site *not* to open a formal investigation. And no such investigation was conducted.
>
> * * *
>
> Olopatadine: Akorn generated yet more fraudulent test results in 2012 that were used in its ANDA filing for olopatadine (an eye medication). An employee at its Cranbury site generated positive stability testing results through inappropriate "testing into compliance," and that Akorn then submitted those results (but not the corresponding out-of-specification results) in an ANDA.
>
> Cyclopentolate: Akorn also generated fraudulent test results in 2013 that were used in its ANDA filing for cyclopentolate (another eye drug). An employee at Akorn's Vernon Hills site made a "deliberate change" in a testing procedure "to force a passing result[.]"

323. Thus, by 2016 and 2017, when the false and misleading Proxy Statements were approved by the Defendants, Defendant Silverberg, who reported directly to Defendant Rai and was the most senior quality official at Akorn, overseeing more than 500 employees at the Company, was already aware of the forged entries. Silverberg instructed the Somerset site *not* to open a formal investigation.

324. In his post-trial opinion, Vice-Chancellor Laster described Akorn as "a company in persistent, serious violation of FDA requirements with a disastrous culture of noncompliance." He explained that:

> ***The systemic failures at Akorn raise questions about the accuracy and reliability of all of its data, regardless of site or product. As a result, Akorn cannot meet its burden to prove to the FDA that its data is accurate***. ***To the contrary, Akorn's products and facilities are known not to comply with cGMP and FDA requirements, as shown by the reports of its own internal audit team***. Akorn does not make products where quality issues can be overlooked until problems arise. As

> Henriksson testified, "[W]e are talking about drugs which are used by people … who are critically ill … [and] many of those products … are going to be injected into people."

325. By reasons of the conduct alleged in this Complaint, the Director Defendants and Rai violated Section 14(a) of the Exchange Act and SEC Rule 14a-9. As a direct and proximate result of the Defendants' wrongful conduct, the Individual Defendants misled or deceived its stockholders by making misleading statements that were an essential link in the matters set forth in the Proxy Statements for which stockholder approval was sought.

326. The misleading information contained in the Proxy Statements was material to Akorn's stockholders in determining whether or not to approve the matters set forth in the Proxy Statements for which stockholder approval was sought.

327. Because of the false and misleading statements in the Proxy Statements, Akorn's shareholders voted to approve the matters set forth in the Proxy Statements for which stockholder approval was sought.

328. Plaintiff, on behalf of Akorn, thereby seeks relief for damages inflicted upon the Company as a result of the false and misleading statements in the Proxy Statements, including the unjustified payment of compensation to Defendants.

329. This action was timely commenced within three years of the date the Proxy Statements and within one year from the time Plaintiff discovered or reasonably could have discovered the facts on which this claim is based.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff demands for a judgment as follows:

A. A determination that this action is a proper derivative action maintainable under the law and that demand was improperly refused;

B. Declaring that Defendants have breached their fiduciary duties to Akorn, including the duty of loyalty;

C. Determining and awarding to Akorn the damages sustained by it as a result of the violations set forth above from each Defendant, jointly and severally, together with prejudgment and post-judgment interest thereon;

D. Directing Akorn to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect the Company and its stockholders from a repeat of the damaging events described in this Complaint, including putting forward for a stockholder vote resolutions for amendments to the Company's by-laws or articles of incorporation, and taking such other actions as may be necessary to place before stockholders for a vote the following corporate governance policies:

1. a proposal to strengthen Board oversight and supervision of Akorn's data integrity and FDA compliance practices;

2. a proposal to strengthen the Company's disclosure controls to ensure material information is adequately and timely disclosed to the SEC, FDA and the public;

3. a proposal to ensure that all Board members take appropriate action to rid the Company of its lawless culture, particularly in the areas of regulatory compliance and data integrity;

4. a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater stockholder input into the policies and guidelines of the Board; and

5. a proposal to permit the stockholders of Akorn to nominate at least three candidates for election to the Board;

E. Extraordinary equitable or injunctive relief as permitted by law or equity, including attaching, impounding, imposing a constructive trust on, or otherwise restricting Defendants' assets so as to assure that Plaintiff, on behalf of Akorn, has an effective remedy;

F. Awarding to Akorn restitution from Defendants, and each of them, and ordering disgorgement of all profits, benefits, and other compensation obtained by Defendants, including the proceeds of insider transactions made in violation of federal and state securities laws;

G. Ordering an accounting of all compensation awarded to the Individual Defendants during the Relevant Period;

H. Awarding to Plaintiff costs and disbursements related to this action, including reasonable attorneys' fees, consultant and expert fees, costs, and expenses; and

I. Granting such other and further relief as the Court deems just and proper.

**JURY DEMAND**

Plaintiff demands a trial by jury on all issues so triable.

Dated: November 6, 2018

WEXLER WALLACE LLP

*/s/ Kenneth A. Wexler*

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*Attorneys for Plaintiff*

**VERIFICATION**

I, Dale Trsar, Trustee of the Dale A. Trsar Trust, verify that the trust is a shareholder of Akorn, Inc. I have reviewed the allegations in this Verified Shareholder Derivative Complaint. As to those allegations of which I have personal knowledge, I believe them to be true; as to those allegations of which I lack personal knowledge, I rely upon my counsel and counsel's investigation, and believe them to be true. Having received a copy of the complaint and reviewed it with counsel, I authorize its filing.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: October 25, 2018

DocuSigned by:
Dale Trsar
93B91A18A024493...

Dale Trsar, Trustee of the Dale A. Trsar Trust